

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA**

IN RE: PHILIPS RECALLED CPAP, BI-LEVEL PAP, AND MECHANICAL VENTILATOR PRODUCTS LITIGATION	:	Master Docket: No. 21-mc-1230-JFC
	:	MDL No. 3014
	:	(Oral Argument Requested)
	:	
This Document Relates to:	:	
	:	
Consolidated Second Amended Class Action Complaint for Medical Monitoring	:	
(ECF No. 815)	:	
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**REPLY BRIEF IN SUPPORT OF PHILIPS RS NORTH AMERICA LLC'S RULE
12(b)(6) MOTION TO DISMISS THE CONSOLIDATED SECOND AMENDED
CLASS ACTION COMPLAINT FOR MEDICAL MONITORING**

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Defendant Philips RS North America LLC (“Respironics”) submits this reply in further support of its motion to dismiss Plaintiffs’ Consolidated Second Amended Class Action Complaint for Medical Monitoring (the “MMSAC”) pursuant to Federal Rule of Civil Procedure 12(b)(6).¹

I. INTRODUCTION

Respironics demonstrated in its opening brief (“MTD”) that the MMSAC should be dismissed because Plaintiffs do not plausibly allege that: (1) they were *actually exposed* to any *particular harmful substance* in any *quantity or concentration*, (2) they are likely to develop any *particular latent disease*, or (3) that *any particular medical monitoring program* exists to detect the latent diseases they allege. Instead of alleging specifics, Plaintiffs allege a laundry list of potential harms including practically every variation of cancer that a person can suffer in addition to other general respiratory ailments,² along with an index of generic categories of common medical tests.³ Alleging increased risk of a limitless host of harms a person could suffer fails to plead a plausible claim. *See, e.g., Heinen v. Royal Caribbean Cruises LTD.*, 806 F. App’x. 847, 849 (11th Cir. 2020) (“threadbare allegations of harm … listing what seems to be every possible injury imaginable” fail to allege a plausible claim).

Plaintiffs’ Brief in Opposition (“Opposition” or “Opp.”) confirms these failures. Plaintiffs admit they cannot allege *actual exposure* to any hazardous substance, let alone exposure in quantities and concentrations exceeding safe thresholds, because Plaintiffs “have no way to determine whether the foam in their individual Device has degraded or off-gassed toxins.” Opp.

¹ Respironics hereby incorporates and does not restate arguments from its Reply Mem. in Support of Motion to Dismiss the Third Amended Class Action Complaint for Economic Losses (ECF No. 1728) and Reply Mem. in Support of Motion to Dismiss the Amended Master Long Form Complaint for Personal Injuries and Damages (ECF No. 1827) to the extent those arguments are applicable here.

² MMSAC ¶ 371.

³ MMSAC ¶ 493.

at 2. Nor do Plaintiffs dispute that they admitted in the MMSAC that they lack a factual basis for their claims by asserting they need a “science panel” to determine whether using the recalled devices has the potential to cause harm.⁴ Though Plaintiffs abandon the “science panel” demand in their Opposition, that does not erase their concession. Opp. at 28.

Plaintiffs’ failure to plausibly allege any of the elements of their claims for medical monitoring compels dismissal of the MMSAC in its entirety. Narrower issues of state law such as whether a present physical injury must be alleged to state a claim further support that conclusion, but are not necessary to grant the Motion. To the extent the Court nevertheless reaches the issue, Plaintiffs’ assertion that this Court can ignore state law applying the traditional tort rule requiring present physical injury defies Third Circuit precedent and should be rejected.

For all these reasons, whether Plaintiffs package their demand for medical monitoring as a claim for negligence, strict liability, failure to warn, breach of warranty, or otherwise, the MMSAC fails to plausibly allege any claims for which relief can be granted. And because Plaintiffs’ own admissions establish that their pleading failures cannot be corrected by amendment, the MMSAC should be dismissed in its entirety and with prejudice.

II. ARGUMENT

A. Plaintiffs’ Failure to Plead the Elements of a Claim for Medical Monitoring Under the Laws of Any Jurisdiction Compels Dismissal.

Plaintiffs agree that to state a medical monitoring claim a plaintiff must at least allege: (1) a significant exposure to a known hazardous substance; (2) the exposure substantially increased the risk that plaintiff will contract a serious latent disease; (3) this increased risk necessitates specific medical testing and monitoring that can detect the latent disease for early treatment; and, (4) this medical monitoring program is different from what would be prescribed in the absence of

⁴ MMSAC ¶ Prayer at p. 202.

the exposure. *See* Opp. at 21-27; *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990). Plaintiffs' conclusory allegations of these elements are "not entitled to be assumed true" and are insufficient to state a claim. *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009). "Plaintiffs must meet the applicable pleading standard by alleging sufficient factual matter to state a claim to relief that is 'plausible on its face.'" *Menkes v. 3M Co.*, No. 17-0573, 2018 WL 2298620, at *12 (E.D. Pa. May 21, 2018) (quoting *Ashcroft*, 556 U.S. at 678). The MMSAC fails to satisfy this standard.⁵

1. Plaintiffs Fail to Sufficiently Plead Actual Exposure to a Hazardous Substance.

Plaintiffs assert "there can be no doubt about actual exposure," and that they "plead actual exposure, not risks of exposure," but conclusory assertions do not satisfy Plaintiffs' pleading burden. Opp. at 22; *see Adamson v. Ortho-McNeil Pharm. Inc.*, No. 06-866, 2007 WL 604790, at *3 (D.N.J. Feb. 20, 2007) (a conclusory statement "express[es] a factual inference without stating the underlying facts on which the inference is based"). Plaintiffs' admission that "users have no way to determine whether the foam in their individual Device has degraded or off-gassed toxins" in effect concedes that Plaintiffs have not plausibly alleged actual exposure to any hazardous substance, because they *cannot* do so. Opp. at 2.

Plaintiffs nevertheless insist that they must have been exposed to hazardous substances

⁵ Plaintiffs do not dispute that they lack standing to assert claims under the laws of Alabama, Alaska, Kentucky, Louisiana, Michigan, Mississippi, South Dakota, Wisconsin, and Wyoming, and disclaim that they are pursuing claims in those jurisdictions. MTD at 30-31; Opp. at 38-39. Plaintiffs' plea to delay dismissal until the class certification stage—for no reason at all—must be rejected. Opp. at 39. *See In re Sensipar (Cinacalcet Hydrochloride Tablets) Antitrust Litig.*, No. 19-md-2895, 2022 WL 736250, at *17 (D. Del. Mar. 11, 2022) (where "the Court . . . has not yet reached the stage of considering class certification, there would be no practical benefit to waiting to decide standing until after a decision on class certification."); *Sheet Metal Workers Loc. 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 211 (E.D. Pa. 2009) (holding that the court must "address[] standing or failure to state a claim before ruling on the class certification and summary judgment motions").

because they used recalled devices at least 30 times, and the devices were recalled because they might manifest a defect that potentially could expose users to hazardous substances. Opp. at 21. “That chain of inferences is inadequate to plausibly plead exposure” to a hazardous substance. *In re Zantac (Ranitidine) Prods. Liab. Litig.*, 546 F. Supp. 3d 1152, 1168 (S.D.Fla. 2021) (holding plaintiffs failed to plausibly allege exposure where they alleged that they consumed medicines that were recalled because some of the medicines tested positive for contaminants).

Respironics’ recall notices do not help Plaintiffs bridge this gap. Those notices explain Philips initiated the recall based on a *possibility* of exposure, not because use of the devices *actually* causes exposure. Specifically, the June 14, 2021 recall announcement stated that “foam breakdown ‘*may* lead to patient harm and impact clinical care,’” MMSAC ¶ 196 (emphasis added), and that there could be a “*potential*” hazard because “under *certain circumstances* the foam *may* degrade,” *id.* at 198 (emphasis added). Respironics’ July 2021 updated notice likewise stated that PE-PUR foam particles potentially *could* contain chemicals including toluene diamine, toluene diisocyanate, and diethylene glycol, but that Respironics at that time *did not know whether the particles actually contained* these chemicals and testing was ongoing. MMSAC Ex. 76. The same notice further stated that the devices *could* emit trace amounts of the volatile organic compounds (VOCs) dimethyl diazene and phenol 2,6-bis (1,1-dimethylethyl)-4-(1-methylpropyl) under certain *extreme* operating conditions. *Id.*⁶

The most recent testing results, which Plaintiffs attach and incorporate into the MMSAC,

⁶ See MMSAC ¶ 196 (adopting Philips’ June 14, 2021 Sleep and Respiratory Care Update: Clinical Information for Physicians, MMSAC Ex. 7) (alleging that “Philips has determined that . . . under certain circumstances . . . the foam may degrade into particles which may enter the device’s air pathway. . . .”); ¶ 207 (adopting Philips’ June 14, 2021 Sleep and Respiratory Care Update: Clinical Information for Physicians, MMSAC Ex. 7) (alleging that “VOCs . . . may be emitted from the sound abatement foam”).

bear this out and show that only a tiny percentage of the recalled devices evidence foam degradation. *See* MTD at 15-19 (citing MMSAC Ex. 111 and linked detailed explanation and December 21, 2022 updated results). This Court cannot assume that Plaintiffs were exposed to hazardous substances based only on statements that the devices' insulation foam "may" degrade and where testing results incorporated into Plaintiffs' factual allegations show it is highly unlikely that Plaintiffs' devices manifested the defect. *See Iqbal*, 556 U.S. at 681-82 ("[C]onclusory" assertions cannot "be assumed true" when contradicted by actual facts in the complaint).

At most, this Court might reasonably infer from the MMSAC's allegations that Plaintiffs were at *risk* of exposure. But alleging mere risk of exposure does not state a claim for medical monitoring. *See, e.g., Cook v. Rockwell Int'l Corp.*, 755 F. Supp. 1468, 1477 (D. Colo. 1991) (medical monitoring claim dismissed because "the allegation of mere risk of exposure and not exposure in fact is inadequate"); *Jacobs v. Osmose, Inc.*, No. 01-944, 2002 WL 34241682, at *3 (S.D. Fla. Jan. 3, 2002) (allegation that plaintiff's deck contained hazardous chemicals held insufficient because plaintiff failed to allege actual exposure to hazardous chemicals).

All of Plaintiffs' claims for medical monitoring fail for this reason and should be dismissed. *See Lafferty v. Sherwin-Williams Co.*, No. 1:17-06321, 2018 WL 3993448, at *5 (D.N.J. Aug. 21, 2018) (dismissing medical monitoring claim for failure to "identify specific substances to which Plaintiffs were *actually* exposed [and] at what levels Plaintiffs were actually exposed") (emphasis in original); *Slemmer v. McGlaughlin Spray Foam Insulation, Inc.*, No. 12-6542, 2013 WL 5655480, at *2 (E.D. Pa. Oct. 17, 2013) ("A plaintiff must allege specific facts which support the elements required" including "exposure greater than normal background levels.").

2. Plaintiffs Fail to Plausibly Allege That Any Exposure Was Significant.

Even if Plaintiffs plausibly alleged actual exposure to hazardous substances, they do not plausibly allege that any exposure was *significant*. For exposure to a hazardous substance to be

significant, it must be of sufficient quantity, concentration, and duration to increase the risk of contracting a latent disease. *Redland Soccer Club, Inc. v. Dep’t of Army of U.S.*, 55 F.3d 827, 846 (3d Cir. 1995) (“‘Significant exposure,’ therefore, refers to an exposure which, either by duration or harm, is sufficient to cause a significantly increased risk. . . .”). Plaintiffs admit they fail to allege exposure to any particular quantity or concentration of any hazardous substance. Opp. at 22. They nevertheless argue they are not required to “allege a specific threshold of exposure that substantially increases the risk of disease.” Opp. at 23. That is not the law for good reason.

Alleging an *insignificant* exposure fails to state a plausible claim because a *de minimis* exposure would not warrant medical monitoring relief. *See Lafferty*, 2018 WL 3993448, at *5 (dismissing medical monitoring claims for failing to plausibly allege significant exposure because plaintiffs failed to allege “at what levels Plaintiffs were actually exposed”); *Slemmer*, 2013 WL 5655480, at *2 (“A plaintiff must allege specific facts which support the elements required” including “exposure greater than normal background levels.”); *see also* Moving Citation Table C (ECF No. 1352 at 49-51) (including necessary elements of exposure in certain jurisdictions). For this reason, decisions like *Riva v. Pepsico, Inc.*, 82 F. Supp. 3d 1045, 1056-57 (N.D. Cal. 2015) and *In re Zantac*, 546 F. Supp. 3d at 1170 hold that to state a plausible claim, plaintiffs must allege they were exposed to hazardous substances in amounts exceeding a threshold beyond which exposure substantially increases the risk of harm. As in *Riva*, Plaintiffs here provide “no context as to the significance and extent of exposure to make the necessary ultimate showing that” medical monitoring is warranted and so fail to allege a plausible claim. *Riva*, 82 F. Supp. 3d at 1057.

Plaintiffs assert that *Riva* and *Zantac* were wrongly decided because they purportedly “conflated” the “evidence necessary for proof at trial with pleading requirements,” but there is no evidence the courts misunderstood their obligations under Rule 12(b). Opp. at 23. Nor do

Plaintiffs cite any case where a court has adopted their undemanding pleading standard that contradicts Supreme Court precedent requiring more than conclusory assertions of the elements.

As a fallback, Plaintiffs ask the Court to assume facts they have not alleged and offer the excuse that they cannot plead specifics because they “cannot and should not open their Devices in an attempt to determine the level of foam degradation.” Opp. at 24. Both arguments fail.

First, Plaintiffs ask the Court to *assume*—based on nothing—that Plaintiffs used their devices for “periods of time sufficient to establish levels of exposure that are hazardous to health,” and for the “minimum duration sufficient to increase their risk.” Opp. at 21-22. But Plaintiffs fail to allege *what* “periods of time” are “sufficient” for “levels of exposure” to be “hazardous,” and fail to allege *what* “minimum duration” is “sufficient to increase their risk.” *Id.* Indeed, they allege no correlation between duration or frequency of use and exposure, and the Court cannot presume that exposure thresholds were exceeded where Plaintiffs fail to allege any thresholds whatsoever. Plaintiffs’ argument must be rejected because “[b]y failing to allege a threshold level of exposure, the Plaintiffs essentially argue that *any level of exposure* ... is sufficient to obtain medical monitoring.” *See In re Zantac*, 546 F. Supp. 3d at 1168 (emphasis added).

Second, Plaintiffs’ excuse that they are unable to assess their devices for themselves is not a reason to presume the truth of Plaintiffs’ conclusory allegations—it is confirmation that Plaintiffs’ allegations lack a factual foundation. *Iqbal*, 556 U.S. at 681-82. This is especially so here because the Opposition fails even to acknowledge that extensive testing of the devices *has been performed*, the results of which Plaintiffs attached to the MMSAC as an exhibit.⁷ These tests

⁷ Where, as here “scientific studies are cited and thus incorporated into the complaint, and where those studies simply do not support the allegations, the Court may find that the ‘deficiencies . . . go to the very heart of the plausibility standard under *Iqbal*’” and dismiss the complaint. *Sabol v. Bayer Healthcare Pharm., Inc.*, 439 F. Supp. 3d 131, 147-51 (S.D.N.Y. 2020); *Kardovich v. Pfizer, Inc.*, 97 F. Supp. 3d 131, 141 (E.D.N.Y. 2015) (“Plaintiffs have chosen to use scientific studies in

found that VOC emissions from the devices were “*below* established limits,” and not “anticipated to result in long-term health consequences,” and that particulate matter emissions from the devices also were within “allowable limits.” MMSAC Ex. 111. The testing results negate any assumption that Plaintiffs were exposed to hazardous substances in excess of safe exposure thresholds, and Plaintiffs’ medical monitoring claims should be dismissed for this reason as well.

3. Alleging a Laundry List of Potential Categories of Diseases Fails to Plausibly Allege Increased Risk of Disease.

Plaintiffs assert they have “allege[]d specific cancers and diseases to specific organs that are linked to specifically identified Foam Toxins,” but that is not so. Opp. at 24. Plaintiffs allege increased risk of a non-exclusive list of broad categories of harms: “cancer of the head, neck, kidneys, liver, brain, pancreas, blood-forming tissue, respiratory system, gastrointestinal system, reproductive system, and lymphatic system; respiratory diseases such as asthma, chronic bronchitis, chronic obstructive pulmonary disease, constrictive bronchiolitis or obliterative bronchiolitis, emphysema, interstitial lung disease, pleuritis, pulmonary fibrosis, sarcoidosis; and chronic sinusitis, chronic rhinitis and other forms of chronic inflammation.” *Id.*; MMSAC ¶ 371.

Plaintiffs’ allegation that using the devices increased the risk of practically every category of cancer and respiratory ailment a human being can suffer fails to state a plausible claim for medical monitoring. *See Slemmer*, 2013 WL 5655480, at *3 (“vague catch-all phrases” like “respiratory ailments” fail to allege a “serious latent disease”); *Lafferty*, 2018 WL 3993448, at *4 (“sweeping allegations of ‘serious latent disease’ do not [] properly put a defendant on notice”).

an effort to raise plausible inferences [of liability] . . . Because the studies cited do not so do . . . all of plaintiffs’ claims fail to meet the standards under [] Rule 12(b)(6”). Here the testing results incorporated into Plaintiffs’ allegations (MMSAC Ex. 111) are the only facts in the MMSAC relevant to the issue of actual exposure to hazardous substances, and Plaintiffs do not dispute that they contradict Plaintiffs’ conclusory exposure allegations.

Plaintiffs cite no case where a court has endorsed such an approach, and they fail to distinguish the cases that have expressly rejected similar laundry list style pleadings. Plaintiffs argue, for example, that *Norfolk & W. Ry. Co. v. Ayers*, 538 U.S. 135, 154 (2003) is distinguishable because that case involved alleged exposure only to one toxin—asbestos—as opposed to multiple toxins, but that is the difference which makes the point. Opp. at 24. The Supreme Court permitted plaintiffs’ claims in *Norfolk* because they alleged an “undisputed relationship between exposure to asbestos sufficient to cause asbestosis, and asbestos-related cancer.” *Norfolk*, 538 U.S. at 154. That is exactly what Plaintiffs fail to allege here.

Nor do Plaintiffs distinguish *Slemmer*, which held that plaintiffs’ allegations of increased risk of “lung damage, and throat, eye and nose irritations” failed to state a claim for medical monitoring. *Slemmer*, 2013 WL 5655480, at *3. There, the court held that alleging risk of “lung damage” was insufficient because it is a general category that can “encompass a host of different diseases, some of which may be patent or discoverable through routine medical checkups.” *Id.* Plaintiffs’ vague allegations of “respiratory diseases,” “other forms of chronic inflammation,” and various broad categories of cancers are even more open-ended and non-specific than the allegations in *Slemmer*, and the same result is warranted here: dismissal.

4. Plaintiffs’ Failure to Allege Any Specific Proposed Medical Monitoring Program Compels Dismissal.

Plaintiffs’ assertion that they have alleged “more than generic allegations” regarding the medical monitoring program they seek is demonstrably false. Opp. at 25. Plaintiffs allege they are entitled to: “blood and laboratory tests; physical examinations; imaging; colonoscopies, endoscopies, and other similar methods for examination; biopsies; pathologic, histologic, and oncologic evaluations; oncologic, histologic, surgical, and other necessary medical consultations; and medical and surgical procedures necessary for diagnosis and treatment.” MMSAC ¶ 382. This

non-exhaustive laundry list of broad, generic categories of commonplace medical procedures does not satisfy Plaintiffs' obligation to plausibly allege that *specific* "[m]onitoring and testing procedures exist which make the early detection and treatment of the disease possible and beneficial." *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d at 852.

Plaintiffs fail to distinguish cases like *Slemmer*, 2013 WL 5655480, at *3, *In re Avandia Marketing, Sales Practices and Products Liability Litigation*, No. 10-2401, 2011 WL 4006639, at *3 (E.D. Pa. Sep. 7, 2011), *Bell v. 3M Co.*, 344 F. Supp. 3d 1207, 1227 (D. Colo. 2018), and *Zantac*, 546 F. Supp. 3d at 1168, where plaintiffs were required to plead with specificity the medical testing that they alleged was reasonably necessary. Plaintiffs' allegations here use more words than the plaintiffs in the foregoing cases but have no more substance and fail for the same reasons.

"Courts overseeing large cases—including those involving medical monitoring claims—have demanded specificity in pleadings before permitting the case to advance further," both because that is what the Federal Rules require and because specificity is critical for discovery and issues of class certification to proceed efficiently. *Zantac*, 546 F. Supp. 3d at 1178; *Cook*, 755 F. Supp. at 1475 ("In a case of this magnitude, a district court must retain the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed."). This Court should do the same in this large case involving medical monitoring claims for the same well-founded reasons. Because Plaintiffs fail to plead facts needed to state plausible claims for medical monitoring, the MMSAC should be dismissed.

B. Most Jurisdictions Require a Present Physical Injury to State a Claim.

1. Plaintiffs' "Present Economic Injury" Argument is Meritless.

Whether a plaintiff states a claim for medical monitoring absent an allegation of present physical injury depends on which state's law governs under the analysis required by *Erie R.R. Co.*

v. Tompkins, 304 U.S. 64 (1938). Respiromics showed that under the laws of most states—including 31 of the 42 states referenced in the MMSAC⁸—Plaintiffs’ medical monitoring claims fail because they allege no present physical injury. For example, as Plaintiffs are now constrained to concede in their recent Notice of Supplemental Authority (ECF No. 1738), the New Hampshire Supreme Court has reaffirmed that “the mere existence of an increased risk of future development of disease is not sufficient under New Hampshire law to constitute a legal injury for purposes of stating a claim for the costs of medical monitoring as a remedy or as a cause of action in the context of plaintiffs who were exposed to a toxic substance but have no present physical injury.” Plaintiffs’ medical monitoring claims accordingly fail under the laws of New Hampshire and all similar jurisdictions that likewise require allegations of physical injury to state a claim.⁹

On the other hand, a small minority of states permit claims for medical monitoring without a present physical injury.¹⁰ The existence of this variation in state law is well known and not controversial. *E.g., Baker v. Croda Inc.*, No. 21-3360, 2022 WL 19010312, at *1 (3d Cir. Oct. 21, 2022) (“Some [states] recognize an increased risk of illness as a cognizable injury warranting recovery, while others do not.”); *Almond v. Janssen Pharmaceuticals, Inc.*, 337 F.R.D. 90, 100

⁸ Moving Citation Table A (ECF No. 1352 at 40-46) (jurisdictions that require present physical injury to state a claim). The relevant law in these states is addressed in further detail in the attached Exhibit A (compendium of the parties’ arguments addressing present physical injury requirement in other states).

⁹ See, e.g., *Metro-N. Commuter R. Co. v. Buckley*, 521 U.S. 424, 439-44 (1997); see also, e.g., *Hinton ex rel. Hinton v. Monsanto Co.*, 813 So. 2d 827, 829 (Ala. 2001); *Wood v. Wyeth-Ayerst Lab’ys, Div. of Am. Home Prod.*, 82 S.W.3d 849, 854–56 (Ky. 2002); *Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 689-97 (Mich. 2005); *Paz v. Brush Engineered Materials, Inc.*, 949 So. 2d 1, 5-6 (Miss. 2007); *Lowe v. Philip Morris USA, Inc.*, 183 P.3d 181, 186 (Or. 2008); *Berry v. City of Chicago*, 181 N.E.3d 679, 688-89 (Ill. 2020); *Brown v. Saint-Gobain Performance Plastics Corp.*, No. 2022-0132, -- A.3d --, 2023 WL 2577257, at *3 (N.H. Mar. 21, 2023).

¹⁰ See Moving Citation Table B (ECF No. 1352 at 47-48) (California, District of Columbia, Florida, Maryland, Missouri, Nevada, Pennsylvania, Utah, Vermont, West Virginia, and Massachusetts). Plaintiffs erroneously add Illinois, Arizona, and Tennessee to this list, see Exhibit A.

(E.D. Pa. 2020) (“a fault line” divides states where “state law permits [plaintiffs] to seek relief through a no-injury medical monitoring claim” and states where such claims are prohibited).

Plaintiffs nevertheless argue that the “distinction” between states that do and do not require a present physical injury “does not matter” to their claims, which is plainly wrong. Opp. at 9. Essentially, Plaintiffs contend that they need not allege a present *physical* injury under *any state’s* law—including states that expressly require a present physical injury—because Plaintiffs’ alleged need to pay future medical monitoring costs is a present *economic* injury. Opp. at 15-16. That argument must be rejected for two fundamental reasons.

First, Plaintiffs ask this Court to discard *Erie* and ignore on-point state court precedents holding that a present physical injury is a required element of every negligence and strict liability claim, including claims seeking medical monitoring costs.¹¹ This the Court cannot do. “A federal court in a diversity case is not free to engraft onto those state rules exceptions or modifications which may commend themselves to the federal court” *Day & Zimmermann, Inc. v. Challoner*, 423 U.S. 3, 4 (1975) (*per curiam*). This Court must faithfully “apply the substantive law of the state whose laws govern the action.” *City of Phila. v. Lead Indus. Ass’n, Inc.*, 994 F.2d 112, 122 (3d Cir. 1993). Conservatively applying state law here compels the conclusion that Plaintiffs’ medical monitoring claims are foreclosed in at least 31 jurisdictions for failure to allege a present

¹¹ See *Brown*, 2023 WL 2577257, at *3; *Parker v. Wellman*, 230 F. App’x 878, 882 (11th Cir. 2007) (neither toxic exposure nor the need for medical monitoring constitute cognizable injury under Georgia law); *Sinclair v. Merck & Co.*, 948 A.2d 587, 595 (N.J. 2008) (holding New Jersey law requires present physical injury); *Caronia v. Philip Morris USA, Inc.*, 5 N.E.3d 11, 16-17 (N.Y. 2013) (holding New York does not permit a claim where the “only ‘injury’ is the ‘financial burden associated with periodic medical monitoring’”); *Curl v. Am. Multimedia, Inc.*, 654 S.E.2d 76, 80-81 (N.C. Ct. App. 2007) (rejecting medical monitoring claim absent physical injury); *Lowe*, 183 P.3d at 186-87 (holding that the need to “undergo periodic medical monitoring” is not a cognizable injury). See also Exhibit A (compendium of the parties’ arguments addressing present physical injury requirement in other states).

physical injury. *See Exhibit A* (compendium of the parties' arguments addressing present physical injury requirement in other states) and Reply Citation Table A (Respirronics' response to Plaintiffs' Citation Table A); *see also M.G. ex rel. K.G. v. A.I. Dupont Hosp. for Child.*, 393 F. App'x 884, 893 n.7 (3d Cir. 2010) (holding that "District Court erred in extending Delaware law beyond the bounds of the recognized medical monitoring claim" absent clear holding from state's highest court).

Second, even if Plaintiffs' argument could be considered, it is unpersuasive because it advocates a radical departure from traditional common law tort principles. While defendants have a general duty to avoid causing *physical* injuries, a defendant owes "*no general duty* to avoid the unintentional infliction of economic loss," *i.e.*, the economic loss doctrine. RESTATEMENT (THIRD) OF TORTS: Liab. for Econ. Harm § 1 (2020) (emphasis added); *see also, e.g., Kingston Shipping Co. v. Roberts*, 667 F.2d 34, 35 (11th Cir. 1982) ("[A] plaintiff suing for an unintentional tort cannot recover 'for economic losses not associated with physical damages.'"); *Harris v. O'Connor Truck Sales, Inc.*, 153 F. Supp. 2d 584, 588 (E.D. Pa. 2001) ("[T]he economic loss doctrine bars a plaintiff from recovering purely economic losses suffered as a result of a defendant's negligent or otherwise tortious behavior"). Because medical monitoring costs not arising from present physical injury are purely economic losses, courts reject Plaintiffs' argument as barred by the economic loss doctrine. *E.g., Henry v. Dow Chem. Co.*, 701 N.W.2d 684, 691 (Mich. 2005) (economic losses incurred by paying for medical monitoring "are wholly derivative of a *possible, future* injury rather than an *actual, present* injury. A financial 'injury' is simply not a *present physical* injury, and thus not cognizable under our tort system.") (emphasis in original); *Lowe*, 183 P.3d at 186 ("the present economic harm that defendants' actions allegedly have caused—the cost of medical monitoring—is not sufficient to give rise to a negligence claim").

Plaintiffs' reconception of medical monitoring as a claim for purely economic losses thus provides no basis for this Court to predict that any state's highest court would permit Plaintiffs to assert medical monitoring claims without alleging a present physical injury. *See Travelers Indem. Co. v. Dammann & Co., Inc.*, 594 F.3d 238, 251-53 (3d Cir. 2010) (predicting that economic loss doctrine would bar expansion of tort liability under state law).

2. Allegations of “Subcellular or other Physiological Change” Do Not Satisfy the Present Physical Injury Requirement.

Plaintiffs argue in the alternative that they have adequately alleged a present physical injury by alleging that use of the devices caused “subcellular or other physiological change.” Opp. at 20 (citing *Donovan v. Philip Morris USA, Inc.*, 914 N.E.2d 891, 901 (Mass. 2009)). Plaintiffs are wrong for three main reasons.

First, Plaintiffs allegations of “subcellular or other physiological change” are wholly conclusory and unadorned by factual detail. Plaintiffs do not explain what they mean by “subcellular damage or physiological change,” how using the devices caused these alleged changes, or why Plaintiffs contend that “subcellular damage or physiological change” requires medical monitoring. Such threadbare contentions must be disregarded. *Iqbal*, 556 U.S. at 678.

Second, for all the reasons explained above, Plaintiffs have not plausibly alleged they were actually exposed to any hazardous chemicals as a result of using the devices, much less that they were exposed to quantities and concentrations of hazardous chemicals that might cause “subcellular damage and physiological change.”

Finally, even courts that permit a medical monitoring claim to proceed on the basis of alleged “subcellular damage or other physiological change” recognize the difference between such allegations and a present physical injury. *E.g., Donovan*, 914 N.E.2d at 900. “Subcellular damage or other physiological change” is an inevitable byproduct of biological functions and is not

necessarily injurious. For “subcellular damage or other physiological change” to constitute a physical injury, Plaintiffs would have to plausibly allege that the changes constitute a physical impairment. *See Wood*, 82 S.W.3d at 855 (present physical injury, like “physical harm” is a bodily impairment, not a mere change). No such allegations appear in the MMSAC.

C. Plaintiffs Fail to Plead a Medical Monitoring Claim Under Massachusetts Law.

In *Donovan*, the Massachusetts Supreme Court held that a claim for medical monitoring costs may be asserted by a plaintiff who has not suffered a present physical injury provided that the plaintiff alleges “subcellular changes that substantially increased the risk of serious disease, illness, or injury.” *Genereux v. Raytheon Co.*, 754 F.3d 51, 55 (1st Cir. 2014) (citing *Donovan*, 914 N.E.2d at 901-02). Plaintiffs do not dispute that their only allegations purportedly meeting this standard are the repeated recitation that each has “suffered subcellular injury or other physiological changes that create and/or increase the risk that Plaintiff will develop cancer and other diseases.” MMSAC ¶¶ 25-88. Such formulaic recitations of the elements do not suffice as they cannot be “assumed true.” *Iqbal*, 566 U.S. at 678, 681.

The only relevant, plausible, non-conclusory allegation in the MMSAC is that each Plaintiff used their device. Unlike the heavy smokers in *Donovan*,¹² however, the MMSAC contains no factual allegations that would permit this Court to assume that such use exposed Plaintiffs to toxins capable of producing physiological change substantially increasing the risk of disease. *Iqbal*, 566 U.S. at 682 (disregarding conclusory assertions contrary to the facts). *Donovan* plainly held that physiological changes that will give rise to a claim for medical monitoring are those that “are warning signs to a trained physician that the patient has developed a condition that indicates a substantial increase in risk of contracting a serious illness or disease and thus the patient

¹² *Genereux*, 754 F.3d at 56 (discussing *Donovan II*).

will require periodic monitoring.” *Donovan*, 914 N.E.2d at 901. Plaintiffs have not plausibly alleged any such changes, and so their medical monitoring claims fail under Massachusetts law.

D. District Courts May Not Invent New State Law Medical Monitoring Claims.

Plaintiffs fail to state medical monitoring claims for which relief can be granted, whether pled as an independent cause of action or as a remedy for other torts. However, Plaintiffs’ independent medical monitoring causes of action under the laws of New Hampshire,¹³ Delaware, Connecticut, Montana, and Colorado, should be dismissed for the additional reason that Plaintiffs do not dispute that these states have never recognized such a cause of action. Opp. at 27-28.

“This Court cannot invent new state law claims.” *Banks v. E.I. du Pont de Nemours and Co.*, No. 19-1672, 2022 WL 3139087, at *9 (D. Del. Aug. 4, 2022) (dismissing claim for medical monitoring improperly asserted as a standalone cause of action in Delaware where “[t]he Delaware Supreme Court has never recognized medical monitoring as a free-standing tort”). Plaintiffs’ independent medical monitoring causes of action under the laws of New Hampshire, Delaware, Connecticut, Montana, and Colorado accordingly should be dismissed. *See id.*; *see also* Exhibit A (attached) (addressing the law of each state in detail).

E. Plaintiffs Fail to State a Claim Under Certain State Product Liability Acts.

Plaintiffs’ claims fail under the New Jersey, Connecticut, Indiana, Kansas, Ohio, Tennessee, and Washington product liability acts (the “PLAs”) because these statutes only permit claims seeking physical injury damages. For all states except Connecticut, Plaintiffs do not dispute that the PLAs require physical injury. They argue instead that allegations of “subcellular injury or

¹³ As Plaintiffs acknowledge in their Notice of Supplemental Authority, the New Hampshire Supreme Court was considering whether to recognize medical monitoring as an independent tort when Plaintiffs filed their Opposition but has since adhered to the traditional rule and rejected such a cause of action. ECF No. 1738; *Brown*, 2023 WL 2577257, at *3.

other physiological change” satisfy this requirement. Opp. at 31-32, 34-38. Plaintiffs repeat this argument in support of their Connecticut PLA (“CPLA”) claim, but also argue that the CPLA uniquely permits claims for “economic injury,” which Plaintiffs assert includes their alleged future need to incur medical monitoring costs. *Id.* at 32-33. Plaintiffs’ arguments are meritless.

The Connecticut Supreme Court expressly held that the CPLA is limited to claims “seeking recompense for personal injury, death or property damage” and does not include claims for “financial loss.” *Gerrity v. R.J. Reynolds Tobacco Co.*, 818 A.2d 769, 776 n.11 (Conn. 2003) (citing Conn. Gen. Stat. § 52-572m (b)). This forecloses Plaintiffs’ “economic injury” argument.

All of Plaintiffs’ PLA claims, therefore, hinge on whether they have alleged physical injury causing the economic damages they seek—medical monitoring costs. As explained above, Plaintiffs’ formulaic allegations of “subcellular damage or other physiological change” are conclusory and insufficient to allege a present physical injury. *Iqbal*, 556 U.S. at 678. Because the MMSAC neither alleges nor seeks redress for any physical injury, Plaintiffs’ State PLA claims should be dismissed.¹⁴

¹⁴ See *Sinclair*, 948 A.2d at 588, 595-96 (PLA requires manifest “physical injury” to establish actionable “harm,” and a claim for medical monitoring costs without physical injury seeks recompense for “potential” for harm); *Miller v. Armstrong World Indus., Inc.*, 817 P.2d 111, 113 (Colo. 1991) (holding product liability exposure claim accrues only after “benign” change manifests into disease); *DeVane v. Arch Wood Prot., Inc.*, 197 N.E.3d 343, 347 (Ind. Ct. App. 2022) (“Because the DeVanes have alleged no past or existing physical harm, their action is not one for product liability”); *AlliedSignal, Inc. v. Ott*, 785 N.E.2d 1068, 1075 (Ind. 2003) (“injury . . . does not occur upon mere exposure”; “only when the disease has actually manifested itself (and therefore could be diagnosed by a reasonably experienced physician) [does] the cause of action accrue[]”); *Harding v. K.C. Wall Prod., Inc.*, 831 P.2d 958, 965 (Kan. 1992) (“action did not accrue until the latent disease was diagnosed”) (relying on Kan. Stat. Ann. § 60-3303(d)(1)); *Queen City Terminals, Inc. v. Gen. Am. Transp. Corp.*, 653 N.E.2d 661, 667 (Ohio 1995) (“tangible physical injury to persons” or “tangible property damage” are required for an OPLA claim); Ohio Rev. Code Ann. § 2305.10(B)(1) (instructing a product claim for latent disease arising from hazardous exposure does not accrue until the disease is diagnosable); *Potts v. Celotex Corp.*, 796 S.W.2d 678, 679, 684 (Tenn. 1990) (TPLA claim does not accrue until disease “could have been diagnosed”); *Koker v. Armstrong Cork, Inc.*, 804 P.2d 659, 664, 669 (Wash. Ct. App.

F. Declaratory Judgment May Not Be Used to Adjudicate Past Conduct.

“Declaratory judgment is inappropriate solely to adjudicate past conduct” or “to proclaim that one party is liable to another.” *Corliss v. O’Brien*, 200 F. App’x 80, 84 (3d Cir. 2006). Plaintiffs argue their claim should not be dismissed because it “relates to future conduct” given the alleged “increased risk of disease” and Plaintiffs’ purported need for future medical monitoring. Opp. at 29. But the only thing the MMSAC asks the Court to declare is “that [Respironics] is liable and responsible for the introduction of the Foam Toxins into Plaintiffs’ and Class members’ bodies.” MMSAC ¶ 739. That is not a proper request for declaratory relief.

That Plaintiffs also seek to recover future medical monitoring costs in the same complaint does not transform their defective demand for declaratory relief into a proper request to define future rights. *Rice v. Electrolux Home Prod., Inc.* does not hold otherwise. No. 4:15-cv-00371, 2015 WL 4545520 (M.D. Pa. Jul. 28, 2015). There, the court held that declaratory relief is unavailable “to adjudicate past conduct” but held that rule did not apply where a defective product has not been recalled and putative class members may be harmed by the product in the future. *Id.* at *10. Here, it is undisputed that the devices have been recalled, and the scenario discussed in *Rice* is inapposite. By its plain terms Plaintiffs’ demand for declaratory relief seeks only adjudication of past conduct and so fails to state a claim.¹⁵

1991) (WPLA claim requires the plaintiff to suffer “physical harm” and claims seeking “damages for a future harm” from a latent disease are not actionable until “injury results”); *Duncan v. Nw. Airlines, Inc.*, 203 F.R.D. 601, 609 (W.D. Wash. 2001) (holding manifest present physical injury is necessary for a claim seeking medical monitoring costs).

¹⁵ See *Meyers v. Garmin Int’l, Inc.*, No. 13-CV-2416, 2014 WL 273983, at *9 (D. Kan. Jan. 24, 2014) (dismissing claim seeking declaration that product is defective because the declaration sought to adjudicate past conduct); *Crown Cork & Seal Co. v. Borden, Inc.*, 779 F. Supp. 33, 35-36 (E.D. Pa. 1991) (dismissing claims seeking declaration that products are not defective).

G. The Court Did Not Permit Plaintiffs to Engage in Claim Splitting.

Plaintiffs do not dispute that certain plaintiffs are engaged in claim splitting—the practice of strategically asserting different claims against the same defendants in multiple complaints. Rather, Plaintiffs argue that: (1) the Court allowed them to do so because the master complaints are merely “administrative tools;” and (2) in toxic exposure/latent disease cases, a subsequent action seeking redress for a physical injury does not accrue until the disease is manifested. Opp. at 39-40. Both arguments are meritless.

First, the master complaints here are not mere “administrative tools,” but the “operative pleading[s] that supersede” plaintiffs’ complaints. *In re Refrigerant Compressors Antitrust Litig.*, 731 F.3d 586, 590 (6th Cir. 2013) (citing cases); *see Respiromics’ Reply Mem. in Support of Motion to Dismiss the Third Amended Class Action Complaint for Economic Losses Under Rule 12(b)(1)* at 24-25 (ECF No. 1727). Accordingly, the master complaints must comply with the federal rules, including the rule against claim splitting. *In Re Atrium Med. Corp.*, No. 16-MD-2753-LM, 2018 WL 11397878, at *4 (D.N.H. Jan. 8, 2018) (“[T]he Master Complaint in this case was meant to be more than a mere administrative tool” where court and parties assumed it would be “subject to motions to dismiss.”); *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 489 (7th Cir. 2020) (MDL “amended consolidated” complaints were not “administrative” where treated as the “legally operative pleadings” because “defendants moved to dismiss the consolidated complaints, not the original pleadings”); *see also Gelboim v. Bank of Am. Corp.*, 574 U.S. 405, 413 n.3 (2015). While this Court has authorized Plaintiffs to file three master complaints, nothing permits them to split the same plaintiffs’ claims across more than one master complaint.

In re Zantac and *In re Juul Labs* do not warrant a different conclusion. Opp. at 39-40. Those cases did not endorse claim splitting in an MDL; they merely deferred ruling on the issue. There is no reason for this Court to defer here, and there are good reasons not to do so. Allowing

Plaintiffs to proceed on the basis of defective master complaints will embed legal error and complicate issues for class certification and bellwether selection. The rule against claim splitting requires Plaintiffs to tailor their master complaints to the claims Plaintiffs are actually asserting. If the same plaintiffs allege both economic loss claims and medical monitoring claims, then it makes no sense—and violates the rules—to artificially divide those claims into two complaints.

Second, unlike in *Donovan*, on which Plaintiffs mistakenly rely, the problem here is not that Plaintiffs are splitting claims for medical monitoring costs and hypothetical *future* claims for personal injuries from latent diseases, should they ever manifest. Opp. at 40; *Donovan*, 455 Mass. at 227, 914 N.E.2d at 902 (“[I]n the context of toxic torts, the single controversy rule does not bar a subsequent action for negligence if one of these plaintiffs actually contracts cancer.”). The claims Plaintiffs have impermissibly split are for two species of economic losses purportedly arising from the same core set of facts: (1) economic losses allegedly arising from the purchase of the devices sought in the Third Amended Class Action Complaint for Economic Losses (ECF No. 785); and (2) economic losses allegedly arising from using the devices sought in the MMSAC. Even if *Donovan*, a state court case, were controlling on this question of federal pleading, it is inapposite. The rule against claim splitting applies and must be enforced.

III. CONCLUSION

For all the foregoing reasons, and those stated in Respiromics’ Motion, the MMSAC should be dismissed with prejudice.

Dated: April 21, 2023

Respectfully Submitted,

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REPLY CITATION TABLE A

REPLY CITATION TABLE A:

Respironics' Reply to Plaintiffs' Opposition Concerning Jurisdictions Requiring a Present Physical Injury for a Claim for Medical Monitoring

States	Respironics' Reply
Arizona	<p><i>Burns</i>, an Arizona intermediate appellate decision, held: “The main issue in this case is whether subclinical asbestos-related injury is sufficient to constitute the actual loss or damage required to support a cause of action. We hold that it is not.” 752 P.2d 28, 29. “There can be no claim for damages for the fear of contracting asbestos-related diseases in the future without the manifestation of a bodily injury.” <i>Id.</i> at 31 (internal citations omitted). <i>Burns</i> then addressed medical monitoring, holding such costs were “a compensable item of damages” in that case without proof of physical injury. <i>Id.</i> at 34. But the court did not specify the claim for which such relief would be compensable without physical injury.</p> <p>In <i>Pounders</i>, the Arizona Supreme Court, applying Arizona law, then held that “[f]or long-latency disease . . . a legally compensable injury does not exist” until “the disease is discoverable . . .” – <i>i.e.</i>, “upon manifestation”, not at the point of subclinical or cellular change. 306 P.3d 9, 12-13. Plaintiffs’ attempt to distinguish the holding based on its context ignores the point: a claim cannot exist until the disease manifests.</p> <p>Given <i>Pounders</i> and the <i>Burns</i>’s internal discrepancy, it was unclear whether <i>Burns</i> was (1) adopting a stand-alone medical monitoring claim, (2) jettisoning the physical injury rule as an element of liability for medical monitoring damages, or (3) merely holding that medical monitoring costs were recoverable through a nuisance claim, which does not require physical injury for liability.</p> <p><i>Quiroz</i> resolved this question while addressing the assertion that <i>Burns</i> held there is a tort duty to protect the public from secondary asbestos exposure. 416 P.3d 824, 832. The court “disagree[d]” and explained that <i>Burns</i> only permitted the recovery of medical monitoring “in the context of a nuisance claim” and “affirmed the superior court’s grant of summary judgment” on the “negligence claim.” <i>Id.</i> at 832-33.</p> <p><i>Restatement (Second) of Torts</i> § 7 (1965) merely defines “injury” as “the invasion of any legally protected interest of another.” As shown above, Arizona, like the <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1 (1998), does not recognize freedom from “economic loss” (medical monitoring costs) caused by unintentional conduct to be a legally protected interest absent physical injury outside the context of a nuisance claim.</p> <p>Further, mere subcellular injury is not actionable injury giving rise to a claim. <i>Pounders</i>, 306 P.3d at 12-13.</p>
Arkansas	<p>Plaintiffs ignore the importance of <i>Dowty</i>. There, the Arkansas Supreme Court reaffirmed the physical injury requirement, explained the extremely high bar to abandoning it, and refused to carve an exception for emotional distress suffered by a bystander who was shot at and witnessed a friend being shot. 385 S.W.3d 117, 120-23 (Ark. 2010). The physical injury requirement is well established in Arkansas. <i>Pennebaker v. Furry Feet Retreat, Inc.</i>, 620 S.W.3d 879, 881-82 (Ark. Ct. App. 2021) (recognizing Arkansas requires present physical injury); Ark. Code Ann. § 16-116-202(5) (West 2016) (defining “product liability action” as an action to recover for “personal injury, death, or property damage . . .”). This precedent makes it unlikely Arkansas would jettison the physical injury rule to permit recovery of medical monitoring costs which are incurred because of a fear of the potential for future disease, not present injury.</p> <p>Even if it adopted the <i>Restatement (Second) of Torts</i> § 7, this would not mean that Arkansas would recognize freedom from “economic loss” (medical monitoring costs) caused by unintentional conduct to be a “legally protected interest” absent physical injury. Such a change of course is beyond the scope of the Court’s <i>Erie</i> prediction authority. Indeed, permitting recovery of economic loss here would be contrary to <i>Restatement (Third) of Torts</i> § 1.</p> <p>Plaintiffs provide no basis from which to conclude their conclusory assertions of subcellular or other physiological change constitute actionable injury under Arkansas law.</p>
Colorado	<p>Colorado adheres to the physical injury requirement, as evidenced in the context of emotional distress. <i>See Boryla v. Pash</i>, 960 P.2d 123, 127-28 (Colo. 1998). It also does not permit a person to “pursue a tort claim for future death, future physical injury.” <i>Open Door Ministries v. Lipschuetz</i>, 373 P.3d 575, 579 (Colo. 2016), modified on denial of reh’g (Jun. 27, 2016) (internal citations omitted).</p> <p>The district court’s prediction in <i>Cook v. Rockwell Int’l Corp.</i> that Colorado would depart from this requirement for medical monitoring costs was made 30 years ago based on an assessment of</p>

REPLY CITATION TABLE A:

Respironics' Reply to Plaintiffs' Opposition Concerning Jurisdictions Requiring a Present Physical Injury for a Claim for Medical Monitoring

States	Respironics' Reply
	<p>policy and evolving law. 755 F. Supp. 1468, 1476-78 (D. Colo. 1991). The court did not analyze Colorado law or recognize the obligation to make <i>Erie</i> predictions against the expansion of liability. <i>Id.</i> Further, the prediction (1) has not been borne out in Colorado law, which still has not permitted claims for medical monitoring without physical injury, and (2) has been held by the U.S. Supreme Court to be “beyond the bounds of currently ‘evolving common law.’” <i>Metro-N. Commuter R. Co. v. Buckley</i>, 521 U.S. 424, 440 (1997); <i>see also Wood v. Wyeth-Ayerst Lab'ys, Div. of Am. Home Prod.</i>, 82 S.W.3d 849, 854–56 (Ky. 2002); <i>Henry v. Dow Chem. Co.</i>, 701 N.W.2d 684, 689-97 (Mich. 2005); <i>Lowe v. Philip Morris USA, Inc.</i>, 183 P.3d 181, 186-87 (Ore. 2008); <i>Berry v. City of Chicago</i>, 181 N.E.3d 679, 688-89 (Ill. 2020); <i>Brown v. Saint-Gobain Performance Plastics Corp.</i>, No. 2022-0132, -- A.3d --, 2023 WL 2577257, at *3 (N.H. Mar. 21, 2023).</p> <p>Even if it adopts <i>Restatement (Second) of Torts</i> § 7, this would not mean that Colorado would recognize freedom from “economic loss” (medical monitoring costs) caused by unintentional conduct to be a “legally protected interest” absent physical injury. Such a change of course is beyond the scope of the Court’s <i>Erie</i> prediction authority. Indeed, permitting recovery of economic loss here would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Plaintiffs provide no basis from which to conclude conclusory assertions of subcellular change constitute physical injury under Colorado law.</p>
Connecticut	<p><i>Doe v. City of Stamford</i> was not interpreting tort law; rather it was interpreting the Connecticut Workers Compensation Act, and its holding is limited to the Act’s defined term “injury.” 699 A.2d 52, 54-57 (Conn. 1997). The court expressly distinguished this limited analysis from the U.S. Supreme Court’s analysis in <i>Buckley</i>, 521 U.S. 424, where the court was interpreting FELA, a “statute that is closely tied to traditional tort principles,” and held those principles do not recognize medical monitoring costs to constitute actionable injury. <i>City of Stamford</i>, 699 A.2d at 57 n.11. Indeed, <i>Martin</i>, 180 F. Supp. 2d 313, 323 (D. Conn. 2002), declined to extend <i>Stamford</i> beyond workers compensation cases as it was unnecessary given Martin’s representation that he was not asserting medical monitoring could be awarded without actual injury.</p> <p><i>Poce</i>, on the other hand, was interpreting Connecticut tort law and held that it requires present physical injury as an element of liability, without which medical monitoring costs are not recoverable. 269 A.3d 899, 908-10 (Conn. App. Ct. 2022). Plaintiff does not dispute this was <i>Poce</i>’s holding, and as an appellate ruling it is “persuasive authority” “not to be disregarded.” <i>Travelers Indem. Co. v. Dammann & Co.</i>, 594 F.3d 238, 244 (3d Cir. 2010) (citation omitted).</p> <p><i>Restatement (Second) of Torts</i> § 7 does not change this analysis. It merely defines “injury” as “the invasion of any legally protected interest of another.” Under <i>Poce</i>, the need for medical monitoring absent a physical injury is not a “legally protected interest.” And none of the decisions Plaintiffs cite holds otherwise. Indeed, <i>Waters</i> illustrates the point by applying the <i>Restatement (Second) of Torts</i> § 7’s definitions and holding Connecticut law requires physical harm for the claim at issue there. 676 A.2d 357, 363-64 (Conn. 1996). And permitting recovery of economic loss here would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Plaintiffs provide no basis from which to determine conclusory assertions of subcellular change constitute physical injury under Connecticut law.</p>
Delaware	<p>The Delaware Supreme Court’s holding in <i>Mergenthaler</i> was plain: “We now turn to plaintiffs’ argument that ‘a claim for the expenses of medically required surveillance and related mental anguish caused thereby is maintainable under Delaware law even if there is no present physical disease.’ As indicated earlier, we disagree.” 480 A.2d 647, 651 (Del. 1984) (emphasis added). <i>In re Asbestos Litig.</i> recognized this, as have other states. 1994 WL 16805917, at *1 (Del. Super. Ct. Aug. 5, 1994); <i>see also Paz v. Brush Engineered Materials, Inc.</i>, 949 So. 2d 1, 6 n.5 (Miss. 2007). Plaintiffs prefer to focus on <i>Mergenthaler</i>’s discussion of <i>Ayers</i>’ as somehow contradicting the plain holding by adopting New Jersey’s abandonment of the physical injury requirement. But <i>Mergenthaler</i> merely distinguished <i>Ayers</i> to illustrate its irrelevance under the facts of the case. <i>Mergenthaler</i>, 480 A.2d at 651; <i>see also In re Asbestos Litig.</i>, 1994 WL 16805917, at *1 (holding there was sufficient evidence of physical injury in the record but declining to decide the compensability of asymptomatic claims); <i>Banks v. E.I. du Pont de Nemours & Co.</i>, No. CV 19-</p>

REPLY CITATION TABLE A:

Respironics' Reply to Plaintiffs' Opposition Concerning Jurisdictions Requiring a Present Physical Injury for a Claim for Medical Monitoring

States	Respironics' Reply
	<p>1672-MN-JLH, 2022 WL 3139087, at *9 (D. Del. Aug. 4, 2022), <i>report and recommendation adopted</i>, 2022 WL 3577111 (D. Del. Aug. 19, 2022) (Delaware torts require present injury)).</p> <p>The cases Plaintiffs cite do not hold otherwise. Indeed, in <i>Brown</i>, the court explained that the claim does not accrue until “a legal injury is sustained.” 820 A.2d 362, 369 (Del. 2003). It then cited both the <i>Restatement (Second) of Torts</i> § 7 and <i>Stagg v. Bendix Corp.</i>, which held that latent disease claims do not accrue until disease manifestation. 472 A.2d 40, 43 (Del. Super. 1984) <i>aff'd</i> 486 A.2d 1150 (Del. 1984). <i>Stagg</i> further held that a mere “change” in physiology is not “a demonstrable injury for which damages are recoverable” unless it produces “deleterious results.” <i>Id.</i> at 42. <i>U.S. v. Anderson</i>, 669 A.2d 73, 77 (Del. 1995) reiterated this.</p> <p><i>Restatement (Second) of Torts</i> § 7 merely defines “injury” as “the invasion of any legally protected interest of another.” The need for medical monitoring absent a physical injury is not a “legally protected interest” in Delaware, as shown above. Though this appears to be a question before the Delaware Supreme Court in <i>Baker v. Croda, Inc.</i>, No. 21-3360, 2022 WL 19010312 (3d Cir. Oct. 21, 2022), Plaintiffs have not identified authority from which the Court could predict Delaware would expand liability by jettisoning the physical injury requirement to permit recovery of economic losses in contradiction of <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1. See <i>M.G. ex rel. K.G. v. A.I. Dupont Hosp. for Child.</i>, 393 F. App'x 884, 893 n.7 (3d Cir. 2010) (citations omitted) (requiring courts to conservatively opt against expanding liability when predicting whether a state would permit a claim for medical monitoring).</p> <p>Plaintiffs also provide no basis from which to determine conclusory assertions of subcellular change constitute physical injury under Delaware law.</p>
Georgia	<p>The Eleventh Circuit recognized that the issues of whether Georgia requires physical injury and whether “subclinical damage” constitutes physical injury are issues of law—not fact—to be resolved on a motion to dismiss. <i>Parker v. Wellman</i>, 230 Fed. App'x 878 (11th Cir. 2007). “To recover for personal injuries under Georgia law, a plaintiff must show that he has suffered ‘injury to life or limb or damage to other property.’” <i>Parker</i>, 230 F. App'x at 881 (quoting <i>Pickren v. Pickren</i>, 593 S.E.2d 387, 388 (Ga. 2004)). This requirement extends to toxic exposure claims. <i>Id.</i> at 882 (quoting <i>Boyd</i>, 381 S.E.2d at 298). Allegations of “subclinical and cellular damage” from exposure do not constitute physical injury until they manifest in “an identifiable physical disease, illness, or impairing symptoms.” <i>Id.</i> Because the plaintiffs made no such allegations of manifest impairment, the district court correctly dismissed the claim for medical monitoring. <i>Id.</i> at 883.</p> <p>Plaintiffs provide no basis from which to depart from <i>Parker</i>'s thorough analysis. Plaintiffs' reliance on <i>Restatement (Second) of Torts</i> § 7 is misplaced, even if Georgia adopted it. Section 7 merely defines “injury” as “the invasion of any legally protected interest of another.” Freedom from “economic loss”—the potential future incurrence of medical monitoring costs—allegedly caused by unintentional conduct is not a “legally protected interest” in Georgia, as shown above. The decisions Plaintiffs cite either do not address the issue or reaffirm the necessity of proving physical harm in the context of the elements of specific torts. See <i>Greenway</i>, 294 S.E.2d at 544 (adopting Restatement (Second) of Torts § 398, including the element of “physical harm”); <i>Huggins</i>, 264 S.E.2d at 192 (adopting Restatement (Second) of Torts § 324A, including the element of “physical harm”). Further, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1. Accordingly, there is no basis from which this Court could make an <i>Erie</i> prediction that expands liability by departing from Georgia's adherence to the traditional physical injury requirement. <i>A.I. Dupont Hosp. for Child.</i>, 393 F. App'x 884, 893 n.7.</p>
Hawaii	<p>Plaintiffs do not dispute that <i>In re Hawaii Fed. Asbestos Cases</i>, 734 F. Supp. 1563 (D. Haw. 1990), concluded Hawaii requires physical injury to state a viable claim for negligent toxic exposure. While Hawaii has carved an exception to this rule for HIV exposure, corpse mishandling, and child molestation, it continues to otherwise adhere to the physical injury requirement to weed out baseless claims. <i>Doe Parents No. 1 v. State, Dep't of Educ.</i>, 58 P.3d 545, 580-82 (Haw. 2002), <i>as amended</i> (Haw. Dec. 5, 2002) (summarizing Hawaii law on physical injury requirement and limited exceptions for emotional distress).</p> <p>While Hawaii has yet to directly address medical monitoring costs, the above precedent supports the conclusion that it would not depart from the physical injury requirement here, and Plaintiffs have not identified decisions that would permit this Court to predict otherwise. <i>A.I. Dupont Hosp.</i></p>

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Respironics' Reply to Plaintiffs' Opposition Concerning Jurisdictions Requiring a Present Physical Injury for a Claim for Medical Monitoring

States	Respironics' Reply
	<p><i>for Child.</i>, 393 F. App'x 884, 893 n.7. <i>Restatement (Second) of Torts</i> § 7, even if adopted by Hawaii, merely defines “injury” as “the invasion of any legally protected interest of another,” and the alleged need for medical monitoring absent a physical injury is not a “legally protected interest” in Hawaii. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p>
Idaho	<p>Plaintiffs do not dispute that “there is no tort until there is an injury” that is “objectively ascertainable,” which means “objective medical proof would support the existence of an actual injury.” <i>Davis v. Moran</i>, 735 P.2d 1014, 1019-20, 1020 n.4 (Idaho 1987). Plaintiffs’ assertion that “the economic loss” of medical monitoring costs satisfies this requirement was rejected in <i>Davis</i>. There, the Idaho Supreme Court held that the claim did not accrue upon exposure or even when a physician recommended testing in June 1983; rather, the claim is only actionable when there is an objectively diagnosable injury (e.g., “spinal damage”). <i>Id.</i> at 1016, 1020, n.4.</p> <p>Plaintiffs’ reliance on <i>Hepburn v. Bos. Sci. Corp.</i>, 2018 WL 2275219 (D. Idaho May 17, 2018) is misplaced. First, district court directed Hepburn to amend her complaint to “strengthen her asserted injury,” which was insufficient to establish injury-in-fact. <i>Id.</i> at 9. Second, the court did not address Idaho law on present physical injury. Third, <i>Hepburn</i> alleged present physical injury: “constant pains in the abdominal region.” <i>Id.</i> at *1.</p> <p>None of the other decisions Plaintiffs cite support a prediction that Idaho would abandon the physical injury requirement here. Indeed, <i>S. H. Kress & Co. v. Godman</i> adopted <i>Restatement (Second) of Torts</i> §§ 395, 404, to permit recovery for “physical harm” for defective product claims. 515 P.2d 561, 563-64 (Idaho 1973).</p> <p>Even if adopted, <i>Restatement (Second) of Torts</i> § 7 is irrelevant because it merely defines “injury” as “the invasion of any legally protected interest of another,” and the need for medical monitoring absent a physical injury is not a “legally protected interest” in Idaho.</p> <p>Plaintiffs provide no basis from which to conclude conclusory assertions of subcellular change constitute physical injury under Idaho law, particularly in light of <i>Davis</i>, 735 P.2d 1014 (Idaho 1987).</p>
Illinois	<p>Contrary to Plaintiffs’ description, the plaintiffs in <i>Berry</i> alleged that they were actually exposed to lead, allegations substantiated by water testing and blood samples. 181 N.E.3d 679, 683-84. Nevertheless, the Illinois Supreme Court held that the plaintiffs failed to state a claim because none alleged “any physical impairment, dysfunction, or physically disabling consequence” from the exposure. <i>Id.</i> at 688. Without “actual or realized harm,” the claim devolves to one seeking compensation for the “increased risk of future harm” and risks clogging the “court dockets . . . with comparatively unimportant or trivial claims.” <i>Id.</i> at 687-88. The Illinois Supreme Court proceeded to reject Plaintiffs’ contention “that the need for medical testing or monitoring” itself is a cognizable injury because it “is simply another way of saying [plaintiffs] have been subjected to an increased risk of harm,” which is not an injury. <i>Id.</i> at 688-89.</p> <p>Plaintiffs’ invocation of the intermediate appellate decision in <i>Lewis</i> is perplexing, given that when the Illinois Supreme Court reviewed the case, it held that the plaintiffs could not recover the costs of lead screening tests because, contrary to Illinois tort law, the plaintiffs failed to allege physical injury or property damage and sought recovery solely of an economic loss (cost of tests) that they did not allege they paid. <i>Lewis v. Lead Indus. Ass’n</i>, 178 N.E.3d 1046, 1049 (Ill. 2020).</p> <p><i>Leslie v. Medline Indus., Inc.</i> explained that “a higher than average cancer risk, without physical injury, is not actionable under <i>Berry</i>.” No. 20-CV-01654, 2021 WL 4477923, at *10 (N.D. Ill. Sep. 30, 2021) (internal citations omitted). And <i>Barnes v. Unilever United States Inc.</i>, reiterated that claims for medical monitoring require “present injury” under <i>Berry</i>. No. 21 C 6191, 2022 WL 2915629, at *2 (N.D. Ill. Jul. 24, 2022) (internal citations omitted).</p> <p>Illinois’s adoption of <i>Restatement (Second) of Torts</i> § 7 does not change this analysis. The need for medical monitoring absent a physical injury is not a “legally protected interest” in Illinois. Indeed, <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1 instructs that the “economic loss” that plaintiffs seek is not recoverable here given the absences of physical injury.</p> <p>Accordingly, Plaintiffs have not provided any basis from which this Court could predict Illinois would depart from the above precedent to permit the recovery of medical monitoring damages in this case. <i>A.I. Dupont Hosp. for Child.</i>, 393 F. App'x 884, 893 n.7. Nor do they provide a basis</p>

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States	Respironics' Reply
	from which to conclude conclusory assertions of subcellular change constitute physical injury under Illinois law.
Indiana	<p>Indiana tort law requires a “compensable injury” as an element of liability. <i>Holiday</i>, 2022 WL 4463342, at *4 (<i>quoting Ryan v. TCI Architects/Engineers/Contractors, Inc.</i>, 72 N.E.3d 908, 913 (Ind. 2017)). In <i>Ott</i>, the Indiana Supreme Court held that claims arising from toxic exposure (asbestos) accrue when “the disease has actually manifested itself,” not upon exposure or resulting subclinical change. 785 N.E.2d 1068, 1075, 1075 n.8 (Ind. 2003) (internal citations omitted). <i>Ott</i>’s holding is applicable to the question here, does an exposure claim under Indiana law exist before the plaintiff manifests a present physical injury (disease), and answers this critical question in the negative. <i>Id.</i>; <i>see also Holiday</i>, 2022 WL 4463342, at *4. Plaintiffs disagree as to <i>Ott</i>’s applicability but offer no explanation as to why.</p> <p><i>In re Zantac(Ranitidine) Prod. Liab. Litig.</i> did not have the benefit of <i>Holiday</i>’s analysis and does not discuss <i>Ott</i>. The decision instead—like Plaintiffs—relies on <i>Gray</i> and <i>Allgood</i> to conclude that Indiana tort law, including negligence, does not require a present physical injury to recover medical monitoring costs. 546 F. Supp. 3d at 1166-67. Further, <i>Allgood</i> relies entirely on <i>Gray</i> to predict medical monitoring costs are recoverable through a <i>nuisance</i> claim without present physical injury. 2005 WL 2218371, at *8. <i>Gray</i> explained that this is because nuisance claims are unique in that the statute does not require “physical damage to person or property.” 624 N.E.2d at 54.</p> <p><i>Restatement (Second) of Torts</i> § 7 is irrelevant, even if it is adopted. Freedom from “economic loss” (medical monitoring) allegedly caused by unintentional conduct is not a “legally protected interest” in Indiana; nor is there reason to believe the Illinois Supreme Court would hold otherwise. Indeed, doing so would contradict <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Moreover, Plaintiffs provide no basis from which to conclude conclusory assertions of subcellular change constitute physical injury under Indiana law, particularly in light of <i>Holiday</i> and <i>Ott</i>.</p>
Iowa	<p><i>Pickrell</i>, 293 F. Supp. 3d 865, involved an asymptomatic plaintiff’s exposure claims caused by an alleged defect in a blood temperature regulating machine, seeking medical monitoring costs, which necessitated an <i>Erie</i> prediction. Because the claims sounded in negligence, they required actual injury as an element in Iowa. <i>Id.</i> at 868 (citing <i>Vossoughi v. Polaschek</i>, 859 N.W.2d 643, 649-50 (Iowa 2015)); <i>see also Niblo v. Parr Mfg., Inc.</i>, 445 N.W.2d 351, 354 (Iowa 1989). Mere exposure creating a need for medical testing does not establish the requisite “present physical injury.” <i>Slaymaker v. Archer-Daniels-Midland Co.</i>, 540 N.W.2d 459, 460-61 (Iowa Ct. App. 1995) (persons exposed to asbestos necessitating testing that revealed no “significant damage” did not suffer physical injury). <i>Pickrell</i> thus predicted that the Iowa Supreme Court would not permit a claim for medical monitoring costs absent physical injury. 293 F. Supp. 3d at 868.</p> <p>Plaintiffs fail to present any basis from which this Court could predict that Iowa would expand liability by abandoning the present physical injury requirement or that it would hold mere exposure or the future incurrence of medical testing costs constitutes such an injury. Even if adopted, <i>Restatement (Second) of Torts</i> § 7 merely defines “injury” as “the invasion of any legally protected interest of another.” The alleged need for medical monitoring absent a physical injury, however, is not a “legally protected interest” in Iowa. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Plaintiffs provide no basis from which to conclude conclusory assertions of subcellular change constitute physical injury under Iowa law.</p>
Kansas	<p>Kansas’s courts have not addressed whether medical monitoring costs may be recovered absent present physical injury. They have, however, long held that claims for damages caused by the risk of future injury must have arisen from a physical injury. <i>Reynolds v. Highland Manor, Inc.</i>, 954 P.2d 11, 13 (Kan. Ct. App. 1998) (applying rule in the context of a claim for emotional damages).</p> <p>To the extent Plaintiffs assert that <i>Burton</i> interpreted Kansas law as carving out an exception to this rule for medical monitoring damages, they are wrong. <i>Burton</i> held that medical monitoring costs were recoverable as a component of damages only if the plaintiff proves the elements of liability, including physical injury. <i>Burrton</i> 884 F. Supp. 1515, 1523; <i>see also Duncan v. Nw.</i></p>

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States	Respironics' Reply
	<p><i>Airlines, Inc.</i>, 203 F.R.D. 601, 607-08 (W.D. Wash. 2001) (recognizing this to be <i>Burton's</i> holding); <i>Witherspoon v. Philip Morris Inc.</i>, 964 F. Supp. 455, 467 (D.D.C. 1997) (same). Where Kansas has permitted the recovery of medical monitoring costs, it did so only where those costs “arose from an existing injury,” as in <i>Cott. Burton</i> 884 F. Supp. at 1523 n.6 (distinguishing <i>Cott v. Peppermint Twist Mgmt. Co.</i>, 856 P.2d 906 (Kan. 1993)).</p> <p>Plaintiffs fail to present any basis from which this Court could predict that Kansas would expand liability by abandoning the present physical injury requirement. Even if adopted, <i>Restatement (Second) of Torts</i> § 7 merely defines “injury” as “the invasion of any legally protected interest of another.” The alleged need for medical monitoring absent a physical injury, however, is not a “legally protected interest” in Kansas. Cf. <i>Canaan</i>, 72 P.3d 911, 916 (“liberty of a guilty criminal” is not a protected interest). Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Plaintiffs also provide no basis from which to conclude conclusory assertions of subcellular change constitute physical injury under Kansas law.</p>
Maine	<p>Plaintiffs baldly misrepresent <i>Higgins</i> and its thorough review of Maine law in the context of exposure related tort claims. First, <i>Higgins</i> did consider both a stand-alone medical monitoring claim and medical monitoring costs as a remedy. 2022 WL 2274876, at *10-11. Second, <i>Higgins</i> recognized that the Maine Supreme Court unequivocally held in <i>Bernier</i> that “to be able to recover in tort, a plaintiff must have ‘suffered an identifiable, compensable injury,’ which requires ‘a manifestation of physical injury . . . sufficient to cause him actual loss, damage or suffering.’” <i>Id.</i> at *11 (quoting <i>Bernier v. Raymark Indus., Inc.</i>, 516 A.2d 534, 542-43 (Me. 1986)). Mere microscopic injury from inhalation is insufficient. <i>Id.</i> (quoting <i>Bernier</i>, 516 A.2d at 543). <i>Higgins</i>, therefore, rejected any assertion that alleged exposure and need for medical monitoring constitute “compensable injury” under Maine law. Third, applicability of <i>Bernier</i>'s holding is not limited to issues of accrual of claims under 14 M.R.S.A. § 221. Rather, the issue required the court to examine Maine tort law generally, and the court held: (1) a tort cause of action requires “identifiable, compensable injury”; (2) the threat of unrealized future harm “is not enough”; (3) the actionable harm in a latent exposure case is “the manifestation of disease in the body”; and (4) “subclinical injury” is not actionable harm. <i>Bernier</i>, 516 A.2d at 542-43.</p> <p>Plaintiffs offer no basis from which to conclude <i>Higgins</i>'s analysis of Maine law is wrong, let alone grounds that would permit this Court to expand Maine tort liability by predicting it would abandon the physical injury requirement here. Even if adopted, <i>Restatement (Second) of Torts</i> § 7 merely defines “injury” as “the invasion of any legally protected interest of another.” Freedom from the “economic loss” of the purported need to incur future medical monitoring costs allegedly caused by unintentional conduct without physical injury is not a “legally protected interest” in Kansas. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p>
Minnesota	<p>Plaintiffs do not deny that “damage is an essential element of a negligence cause of action” that is not satisfied by the mere “threat of future harm.” <i>Reliance</i>, 322 N.W.2d 604,607. Nor do they deny that “Minnesota does not recognize” “a claim of increased risk of cancer.” <i>Woyke</i>, 420 N.W.2d 624, 625, 627-28. Rather, they contend that <i>Bryson</i> held Minnesota permits claims for medical monitoring without proof of present physical injury. <i>Bryson</i>, however, recognized that claims seeking medical monitoring require “present injury.” 573 N.W.2d at 720-21. The question in <i>Bryson</i> was whether the alleged “chromosome damage” was a “real and present physical and biologic injury” and this presented a question of fact. <i>Id.</i> at 721.</p> <p><i>Bryson</i> did not hold that any subcellular or other physiological change meets this requirement. Yet, this conclusory allegation is all that each Plaintiff formulaically alleges regarding his or her injury. Physiological change is a constant part of life, particularly at the subcellular level. Without further explication, Plaintiffs have not pled a plausible present injury under Minnesota law. And there is no basis from which this Court could predict that Minnesota would expand liability by abandoning the present injury requirement. Even if adopted, <i>Restatement (Second) of Torts</i> § 7 merely defines “injury” as “the invasion of any legally protected interest of another.” Freedom from the “economic loss” of the purported need to incur future medical monitoring costs allegedly caused by unintentional conduct without physical injury is not a “legally protected interest” in Minnesota. Indeed, holding otherwise would contradict <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p>

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States	Respironics' Reply
Montana	<p>Here, the Court is obliged to predict whether the Montana Supreme Court would permit a claim for medical monitoring costs without present physical injury. “[T]he Montana Supreme Court has not recognized” such a claim (<i>Lamping</i>, No. DV-97-85786, 2000 WL 35751402 (Mont. Dist. Ct. Feb. 2, 2000) or provided “guidance . . . regarding medical monitoring” (<i>In re Zantac Prods. Liab. Litig.</i>, 546 F. Supp. 3d 1152, 1167). Montana requires present physical injury; exposure alone is insufficient. See <i>Schelske v. Creative Nail Design, Inc.</i>, 933 P.2d 799, 803-04 (Mont. 1997) (explaining “physical harm” is an element of exposure claims arising from alleged product defect and requiring Plaintiff to identify specific injuries/illnesses caused by alleged toxic exposure). <i>Lamping</i>, a trial-level decision that was expressly limited to its facts and has never been cited in a Montana case, did not discuss this requirement and provides no basis for the Court to depart from its obligation to avoid expanding state tort law. 2000 WL 35751402. <i>In re Zantac</i>, reached this same conclusion after reviewing Montana law, rejecting the same <i>Lamping</i>-based argument Plaintiffs assert here. <i>In re Zantac</i>, 546 F. Supp. 3d at 1167.</p> <p>Consequently, Plaintiffs identify no basis from which this Court could predict that Montana would expand liability by abandoning the present physical injury requirement. Even if adopted, <i>Restatement (Second) of Torts</i> § 7 is irrelevant. Freedom from the “economic loss” of the purported need to incur future medical monitoring costs allegedly caused by unintentional conduct without physical injury is not a “legally protected interest” in Montana. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Plaintiffs also provide no basis from which to conclude conclusory assertions of subcellular or other physiological change constitute physical harm under Montana law. In the case they cite, <i>Lindsay Drilling & Contracting</i>, the Montana Supreme Court was interpreting an insurance policy’s use of the term “injury,” not analyzing the elements of a tort claim. 676 P.2d 203, 205-206. And even there, the court recognized that the insurance policy required loss or detriment to the claimant—<i>i.e.</i> “harm”—not mere “physical change or alteration.” <i>Id.</i> at 205.</p>
Nebraska	<p>Nebraska has yet to address medical monitoring. However, it adheres to the present physical injury requirement for negligence claims. <i>Avila</i>, No. 4:04-cv-03384-RGK-CRZ, 2007 WL 2688613, at *1 (D. Neb. Sep. 10, 2007) (“damages are an essential element” under Nebraska law and relief cannot be provided absent “present physical injury”). As explained in <i>Ward v. City of All.</i>, 417 N.W.2d 327 (Neb. 1988), toxic exposure claims accrue only after the injury “manifest[s]” itself. <i>Id.</i> at 328, 330. Accordingly and given the obligation not to expand state tort law in making <i>Erie</i> predictions, the courts have predicted that Nebraska would require present physical injury to state a claim for medical monitoring costs. <i>Trimble</i>, 232 F.3d 946, 963 (8th Cir. 2000).</p> <p>This court has the same obligation to avoid expanding Nebraska’s tort liability without substantial evidence that the Nebraska Supreme Court would do so. <i>A.I. Dupont for Hosp. Child.</i>, 393 F. App’x 884, 893 n. 7. Plaintiffs identify no such authority, let alone any that would permit this court to disagree with the Eighth Circuit’s assessment of Nebraska law. Even if adopted, <i>Restatement (Second) of Torts</i> § 7 merely defines “injury” as “the invasion of any legally protected interest of another.” Freedom from the “economic loss” of the purported need to incur future medical monitoring costs allegedly caused by unintentional conduct without physical injury is not a “legally protected interest” in Nebraska. Claims for negligent exposure, instead, require damages. <i>Brown ex rel. Watts v. Soc. Settlement Ass’n</i>, 610 N.W.2d 9, 11 (Neb. 2000). And where the assertion is a latent disease, as is the case here, damages mean a manifested illness, not the mere subcellular or other physiological change Plaintiffs allege in their complaint. <i>Ward</i>, 417 N.W.2d at 328, 330. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p>
New Hampshire	<p>On March 21, 2023, the New Hampshire Supreme Court issued its decision answering the certified questions, rejecting Plaintiffs’ arguments. <i>Brown</i>, --- A.3d ---, No. 2022-0132, 2023 WL 2577257 (N.H. Mar. 21, 2023). There, the court held that New Hampshire tort law requires present physical injury to state a viable claim. <i>Id.</i> at *2-3. The court further rejected Plaintiffs’ argument that the economic loss arising from the purported need to incur medical monitoring costs in the future is not an actionable injury. <i>Id.</i> “[T]he plaintiffs’ characterization of their ‘injury’ as ‘the present need for and cost of diagnostic testing’ conflates ‘an allegation of ‘injury,’ which is ‘an instance of actionable harm,’ with ‘a claim for ‘damages,’ that is, ‘a sum of money awarded to one who has suffered an injury.’” <i>Id.</i> at *2. In making this conflation, “the</p>

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States	Respironics' Reply
	<p>plaintiffs effectively conceded that they do not, at present <i>have</i> an injury.” <i>Id.</i> (emphasis in original).</p> <p>For their final argument, Plaintiffs provide no basis from which to predict conclusory assertions of subcellular or other physiological change constitute actionable harm under New Hampshire law. Indeed, <i>Brown</i> instructs that actionable injury requires harm, not just change. <i>Id.</i> at *2.</p>
New Jersey	<p>Plaintiffs do not dispute that <i>Sinclair</i>, 948 A.2d 587 (N.J. 2008), held that all claims falling within the scope of the New Jersey Product Liability Act require present physical injury, including those seeking medical monitoring costs. Nor do they dispute that <i>Sinclair</i> rejected the argument that “the costs of testing for contamination and of medical treatment are actionable harms under the [NJPLA]” as one that would need to be “directed to the Legislature.” <i>Id.</i> at 591, 595. Rather, they contend that their claim for express warranty—and only this claim—falls outside the NJPLA’s scope.</p> <p>As explained in Philips’ briefing on the motion to dismiss the economic loss complaint, Plaintiffs’ express warranty claims fall outside the scope of the warranty, which does not extend to design defects. Regardless, Plaintiffs other claims require present physical injury. For these, Plaintiffs contend that their allegations of subcellular or other physiological change satisfy the NJPLA’s “manifest injury” requirement. Cf. <i>Sinclair</i> 948 A.2d at 588-89. But Plaintiffs identify no authority supporting this position. The injury they allege is not “manifest” but instead appears to exist only at the subclinical level. If it is/were otherwise, Plaintiffs need to plead the facts to establish that.</p>
New Mexico	<p>Plaintiffs do not dispute that their claims require them to plead and prove “actual harm or damage.” <i>Sanchez</i>, 877 P.2d 567, 573 (N.M. 1994). Rather, they contend that they “have harm and damage in the form of economic loss,” specifically the costs they alleged that they need to spend for “diagnostic testing for the early detection of disease.” Generally, however, there is no duty “to avoid the unintentional infliction of economic loss” under the <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1, which New Mexico has adopted. <i>Nat. Roofing, Inc. v. Alstate Steel, Inc.</i>, 366 P.3d 276, 278 (N.M. App. 2015).</p> <p>As explained in <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1 cmt. d, § 3 recognizes an exception to this rule for medical malpractice actions, where there are inherent limits to the liability imposed and there is an information imbalance. The decision Plaintiffs cite, <i>Mendez</i>, 805 P.2d 603 (N.M. 1991), falls into this unique exception and has been so limited. See <i>Provencio v. Wenrich</i>, 261 P.3d 1089, 1096-97 (N.M. 2011) (limiting <i>Mendez</i> to when a doctor botches a sterilization, does not disclose the failure, and the patient has a child incurring economic loss from raising the child). Here, Plaintiffs are not alleging professional negligence. Rather, they are alleging exposure “which may, in the future lead to an injury,” for which they seek compensation—specifically, the costs of lifelong testing to assuage those fears. In <i>Alberts v. Schultz</i>, the New Mexico Supreme Court disapproved of such claims, indicating they are not cognizable in the absence of physical injury. 975 P.2d 1279, 1285 (N.M. 1999).</p> <p><i>Restatement (Second) of Torts</i> § 7 is irrelevant. Freedom from the “economic loss” of the purported need to incur future medical monitoring costs allegedly caused by unintentional conduct without physical injury is not a “legally protected interest” in New Mexico, and Plaintiffs have not identified any basis from which this Court could predict New Mexico would expand liability to create such a legally protected interest.</p>
New York	<p>After summarizing the development of New York law on the issue, the Second Circuit held: (a) “an action for personal injury cannot be maintained ‘absent allegation of <i>any</i> physical injury’;” (b) “it is, however, sufficient to allege ‘<i>some</i> injury’;” and (c) “to meet the requirement to plead ‘<i>some</i>’ physical injury, it is sufficient to allege that ‘in the plaintiff’s body’ there is either a ‘clinically demonstrable presence of toxins’ ‘or <i>some</i> physical manifestation of toxin contamination.’” <i>Benoit</i>, 959 F.3d 491, 501 (emphasis in original).</p> <p>Given that Plaintiffs appear to agree that this is the established test in New York, it is not clear why they argue—without support—that New York would abandon this test to permit a claim for medical monitoring costs based purely on the alleged “economic loss” of alleged future medical monitoring costs. Regardless, <i>Caronia</i> expressly rejects Plaintiff’s argument. 5 N.E.3d at 16-17 (holding New York would not permit a claim where the “only ‘injury’ is the ‘financial burden associated with periodic medical monitoring’”).</p>

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	<p><i>Caronia</i> also rejected Plaintiffs' argument that the "allegation of subcellular injury is sufficient to constitute physical manifestation of toxic contamination." The concept of permitting medical monitoring claims based on alleged subcellular injury indicative of a condition substantially increasing the risk of a latent disease arises from the Massachusetts Supreme Court's decision in <i>Donovan v. Philip Morris USA, Inc.</i>, 914 N.E.2d 891, 901-03 (Mass. 2009). <i>Caronia</i> regarded <i>Donovan</i> to have abandoned "the physical injury requirement," and for this reason it was a decision New York law rejected for sound reasons. 5 N.E.3d 11, 17-18.</p> <p>The question, therefore, is whether Plaintiffs have plausibly alleged that each of them has a clinically demonstrable presence of toxins in their body or a physical manifestation of toxin contamination. The <i>Benoit</i> plaintiffs met this standard by alleging blood test results. 959 F.3d at 501-02. Plaintiffs identify no such allegation in their complaint, which contains no Plaintiff-specific allegations of injury, and they provide no basis from which to conclude they could cure this deficiency if given leave to amend.</p>
North Carolina	<p>In <i>Curl</i>, the court held that medical monitoring costs are merely another form of relief, available if the plaintiff proves liability, including "present injury." 654 S.E.2d 76, 81. The <i>Curl</i> plaintiffs, however, had no manifested physical injury, arguing instead that "traditional tort law" permits claims based on "(1) infliction of a loss of chance of continued health/increased risk of serious disease; (2) an invasion of personal autonomy, specifically of <i>the right not to be compelled to undergo heightened medical monitoring for the remainder of their lives</i>; and (3) the instilling of fear of cancer or other deadly disease." <i>Id.</i> at 80-81 (emphasis added). The court <u>rejected</u> these arguments, holding North Carolina requires present injury and any attempt to change that should be directed to the legislature. <i>Id.</i> at 81. The <i>Priselac</i> district court recognized this to be the plain holding of <i>Curl</i> and correctly surmised that <i>Curl</i> dictated the requisite <i>Erie</i> prediction. No. 7:20-CV-190-D, 2022 WL 909406, at *3 (E.D.N.C. Mar. 28, 2022).</p> <p>In response, Plaintiffs argue that North Carolina follows the <i>Restatement (Second) of Torts</i> § 7, <i>Priselac</i> ignored this, and § 7 would permit a claim for medical monitoring—without present physical injury—based on "economic loss" Plaintiffs may incur based on their purported need for medical monitoring. <i>Curl</i> <u>rejected</u> this argument, as explained above. The purported need for medical monitoring based on a risk of harmful exposure and future disease, without present physical injury, is "not a legally protected interest" in North Carolina. See <i>Priselac</i>, 2022 WL 909406, at *4. None of the decisions Plaintiffs reference hold otherwise or support a contrary conclusion. Indeed, N.C. Gen. Stat. § 1-52(16) states that claims for latent diseases do not accrue until "bodily harm" is "apparent."</p>
Ohio	<p>In <i>Day</i>, the federal district court recognized: (1) asymptomatic claims for future medical monitoring costs seek to recover based "on the chance that an injury has been sustained"; and (2) Ohio does not allow claims based on the "risk of disease" as opposed to a present injury. 851 F. Supp. 869, 879. Nevertheless, the district court declared: "if the Plaintiffs can establish liability and an increased risk of disease, they will be entitled to medical monitoring." <i>Id.</i> at 881. While it is not clear whether the court was making an <i>Erie</i> prediction or simply believed it was entitled to create state law, the court predicated this expansion of tort liability on (1) decisions in other courts (D.C., Utah, and California) and (2) a belief that it was in the interest of public policy. <i>Id.</i> at 880-81. What is clear, is that <i>Day</i>'s declaration was not supported by any Ohio precedent. It was in spite of it, admittedly.</p> <p>Here, the Court is obligated to faithfully apply Ohio law, avoid engrafting onto state law exceptions that the federal court finds commendable, and opt for the interpretation that "restricts liability, rather than expands it." <i>A.I. Dupont Hosp. for Child.</i>, 393 F. App'x 884, 893 n.7. Because <i>Day</i> took the opposite approach, this Court cannot follow it.</p> <p>As explained in <i>Riston</i>, Ohio courts have not addressed whether Ohio law permits claims for medical monitoring arising solely from exposure without present physical injury. 777 N.E.2d 857,866. Plaintiffs do not dispute <i>Riston</i>'s assessment that permitting such a claim would require "a change in Ohio law." <i>Id.</i> Indeed, Plaintiffs admit that Ohio does not permit recovery economic losses if they do not arise from "tangible physical injury to persons" or property (<i>Queen City Terminals</i>, 653 N.E.2d 661, 667), and they admit that the future costs of the medical monitoring sought here are "economic losses."</p> <p>Plaintiffs instead argue that the need to incur those costs is caused by "damage to Plaintiffs' property, their Devices." Plaintiffs offer no clarification on the nature of this "damage" or its purported causal connection to the alleged need to incur medical monitoring costs. Nor is any</p>

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	<p>connection apparent, given the lack of Plaintiff-specific allegations of device damage, let alone Plaintiff-specific allegations of physical injury, causing any need for medical treatment, including any medical testing. In sum, Plaintiffs are asserting claims based solely on the risk of past exposure allegedly increasing the risk of future disease and are seeking to recover indirect economic costs not yet incurred that do not arise from physical injury. Such claims are not cognizable under Ohio law, as explained above.</p> <p>None of the decisions Plaintiffs reference instruct otherwise. <i>Fernald</i> was resolved by a settlement that was preceded and facilitated by a non-binding “summary jury trial” awarding medical monitoring costs, which provides no insight on Ohio law. 1989 WL 267039, at *2. <i>Elmer</i> blindly relies on <i>Day</i>. <i>Elmer</i>, 127 F. Supp. 3d 812, 825. <i>Wilson</i> reinstated the trial court’s denial of class certification and did not opine on the need to prove present physical injury. 817 N.E.2d 59, 66. And the remainder are cited to support the argument that Ohio follows the <i>Restatement (Second) of Torts</i> § 7. But freedom from the “economic loss” of the purported need to incur future medical monitoring costs allegedly caused by unintentional conduct without physical injury is not a “legally protected interest” in Ohio. And Plaintiffs have not identified any basis from which this Court could predict Ohio would expand liability to create such a legally protected interest or recognize Plaintiffs’ conclusory assertions of subcellular or other physiological change constitute actionable harm under Ohio law.</p>
Oklahoma	<p>Plaintiffs do not dispute that Oklahoma has not decided claims seeking to recover medical monitoring costs are viable without present physical injury. Indeed, in <i>Reece v. AES Corp.</i> the Tenth Circuit reviewed and held that present physical injury is required. 638 F. App’x. 755, 775-76 (10th Cir. 2016). <i>Reece</i> then rejected arguments (1) that concern about future risk constitute cognizable injury and (2) that the formulaic listing of conditions consistent with exposure sufficed to plausibly allege cognizable physical injury. <i>Id.</i> at 776-78.</p> <p>Plaintiffs, instead, urge this Court to predict that Oklahoma would expand tort liability to permit asymptomatic claims for medical monitoring costs based on the expectation that it would adopt the <i>Restatement (Second) of Torts</i> § 7. Even if adopted, § 7 merely defines injury as the invasion of a “legal protected interest.” But the purported need for medical monitoring based on a risk of harmful exposure and future disease, without present physical injury, is “not a legally protected interest” in Oklahoma, and Plaintiffs identify no authority supporting the contrary conclusion. See <i>In re Allergan Biocell Textured Breast Implant Prod. Liab. Litig.</i>, 537 F. Supp. 3d 679, 763-64 (D.N.J. 2021) (citing <i>Taylor v. Michelin N. Am., Inc.</i>, No. 14-CV-293-JED-FHM, 2018 WL 1569495 at *7 (N.D. Okla. Mar. 30, 2018); <i>Reece v. AES Corp.</i>, No. CIV-12-0457-JH, 2014 WL 61242 at *7 (E.D. Okla. Jan. 8, 2014), <i>aff’d</i>, 638 F. App’x 755 (10th Cir. 2016)).</p> <p>Further, Plaintiffs provide no basis from which to conclude conclusory assertions of subcellular or other physiological change constitute actionable harm under Oklahoma law.</p>
Oregon	<p>The Oregon Supreme Court rejected Plaintiffs’ arguments in <i>Lowe</i>, 183 P.3d 181. There, the plaintiff, who did not allege “present physical harm,” asserted negligence claims based on the manufacture and sale of cigarettes caused her to have a “significantly increased risk” of cancer and, as a result, “it was ‘reasonable and necessary’ for her to undergo ‘periodic medical screening.’” <i>Lowe</i>, 183 P.3d at 182-83. The court affirmed the dismissal of the complaint because Oregon requires present physical injury. In reaching this decision, the court expressly rejected Plaintiffs’ arguments that a viable claim could be based on: (1) the significantly increased risk of cancer itself; and (2) “the economic cost” of medical monitoring “constitutes a sufficient present harm.” <i>Id.</i> at 184. “[A] plaintiff must suffer harm ‘to an interest of a kind the law protects against negligent invasion’ to state a claim. <i>Id.</i> The mere threat of physical harm is insufficient to constitute an actionable injury. <i>Id.</i> The threat only becomes actionable when it manifests into “present physical harm.” <i>Id.</i> at 185. The court also held Plaintiffs’ second argument contradicted Oregon law because the costs of medical monitoring are economic losses that are not actionable absent a special duty or physical injury to person or property. <i>Id.</i> at 186. Justice Walters’s concurrence agreed the claim failed because there was no alleged “present physical harm.” <i>Id.</i> at 187. She then opined that physical harm should include “detectable physical effects” from negligent exposure to a harmful substance. <i>Id.</i> at 188. Nevertheless, she concurred in the result: simply alleging the exposure that comes with smoking a pack every day for five years does not establish the necessary physical harm to state a claim.</p>

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	Accordingly, <i>Lowe</i> forecloses both of Plaintiffs' arguments. Neither the economic loss of future medical monitoring costs nor non-detectable subcellular or other physiological change satisfy the present physical harm requirement demanded by Oregon tort law.
Puerto Rico	Plaintiffs do not dispute that Puerto Rican tort law requires proof of actual damages to state a viable claim. Instead, they argue that Puerto Rico would adopt <i>Restatement (Second) of Torts</i> § 7 and because of this, would hold the “economic loss” of the alleged future need to incur medical monitoring costs satisfies the actual damage requirement. Section 7, however, merely defines injury to constitute the invasion of a “legal protected interest.” Under the <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1, there is “no general duty to avoid the unintentional infliction of economic loss on another,” which is commonly referred to as the economic loss doctrine. <i>See also Isla Nena Air Servs., Inc. v. Cessna Aircraft Co.</i> , 449 F.3d 85, 90-92 (1st Cir. 2006) (predicting Puerto Rico would adopt and apply the economic loss doctrine in product defect cases). Plaintiffs do not identify any authority that would permit this Court to predict Puerto Rico would expand liability to permit claims premised on the risk of exposure that may increase the risk of a future disease and/or the future incurrence of the economic loss of medical monitoring costs. Nor do they provide any basis from which to conclude conclusory assertions of subcellular or other physiological change constitute actionable damage under Puerto Rico law.
Rhode Island	<p>In Rhode Island, “the possibility of contracting cancer resulting from mere exposure to a carcinogen, although potentially increasing one’s risk of developing cancer, is too tenuous to be a viable cause of action.” <i>Kelley</i>, 768 A.2d 425, 430. Thus, “in the absence of physical manifestation” (i.e., “symptomatology”), a plaintiff cannot “establish a <i>prima facie</i> case of negligence as a matter of law.” <i>Id.</i> at 430, 431. Plaintiffs’ attempt to characterize <i>Kelley</i>’s holding as being limited to claims for emotional distress ignores the plain language of the holding. The Rhode Island superior court recognized this in <i>Miranda</i>, No. PC04-2210, 2009 WL 3515196, holding an asymptomatic plaintiff cannot assert a claim for medical monitoring costs under <i>Kelley</i>. <i>Id.</i> at *8 (discussing <i>Kelley</i>, 768 A.2d 425).</p> <p>Plaintiffs do not identify any authority that would permit this Court to expand Rhode Island tort liability by predicting it would reverse course from <i>Kelley</i> and permit claims for medical monitoring absent physical manifestation of disease or illness. Even if adopted, the <i>Restatement (Second) of Torts</i> § 7’s definition of injury merely extends to invasions of a “legally protected interest.” <i>Kelley</i> plainly rejected the argument that freedom from exposure to harmful substances is a legally protected interest. Further, the <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1 and <i>Miranda</i> support the conclusion that freedom from economic loss, including costs associated with medical monitoring, is not a legally protected interest, and Plaintiffs cite no case to the contrary. In the lone substantive decision they reference, <i>Emerson</i>, the plaintiff <u>did</u> suffer physical harm, including the pains of delivery and an “additional invasive medical treatment,” and the court <u>rejected</u> recovery of economic losses, namely the costs of rearing the child to adulthood. 689 A.2d 409, 411, 413. Plaintiffs’ assertions to the contrary are unsupported and mistaken.</p>
South Carolina	<p>Plaintiffs do not dispute <i>Rosmer</i>’s recognition that South Carolina does not permit a stand-alone medical monitoring claim. No. CIV.A. 9:99-228018RB, 2001 WL 34010613, at *5 (D.S.C. Mar. 30, 2001). Medical monitoring costs, instead, are merely a form of damages potentially recoverable if liability is established on the elements of another claim. Where, as here, the plaintiff asserts liability arising from an alleged product defect, South Carolina law provides no remedy absent “physical harm to person or property” other than the product. <i>Sapp</i>, 687 S.E.2d 47, 49-50; S.C. Code Ann. § 15-73-10 (product defect damages are limited to “physical harm”).</p> <p>Plaintiffs claim to “have suffered property damage” but do not identify damage to property other than their devices. Nor have they identified any basis from which to conclude that their conclusory assertions of subcellular or other physiological change satisfy South Carolina’s “physical harm” requirement. To the extent Plaintiffs are arguing that this requirement does not apply to products posing serious risk of physical harm, <i>Sapp</i> held that the serious risk exception only applies to residential houses. <i>Sapp</i>, 687 S.E.2d at 50.</p> <p>Moreover, even if adopted, the <i>Restatement (Second) of Torts</i> § 7’s definition of injury would not support the conclusion that South Carolina would permit a claim premised on purported “economic loss” caused by the potential future incurrence of medical monitoring costs. <i>Sapp</i> definitively rejects product liability claims premised only on economic loss. 687 S.E.2d at 49-50. This is echoed by the <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1’s recognition that there is “no general duty to avoid the unintentional infliction of economic loss on another.”</p>

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Tennessee	<p>In Tennessee, “cognizable damage” is necessary for claim, and where the claim arises from the risk of future injury, “there must be a reasonable degree of medical certainty that the plaintiff will develop a disease in the future as a result of the injury.” <i>Potts</i>, 796 S.W.2d 678, 681 (internal citations omitted). Consequently, a claim arising from a latent disease caused by toxin exposure does not exist “until that condition [is] diagnosed, or reasonably could [be] diagnosed.” <i>Id.</i> at 684. Reviewing and applying Tennessee precedent, <i>Jones</i> held that Tennessee requires “present injury or loss to maintain an action” to recover the costs of “testing for the development of a possible future injury.” No. 1:00 CV 0777, 2000 WL 33727733, at *8.</p> <p><i>Sutton</i>, 419 F.3d 568, did not hold otherwise. Rather, the court held that an increased risk of future harm suffices for Article III standing. <i>Id.</i> at 574-75. The court expressly declined to reach the issue of whether Tennessee would allow a claim for medical monitoring without manifested physical injury. <i>Id.</i> at 575-76.</p> <p>Neither <i>Sutton</i>’s dicta discussion of Tennessee’s “murky” law in footnote 7 nor the cases it cites provide sufficient grounds for this Court to make an <i>Erie</i> prediction that would expand liability to permit recovery without present physical injury. 419 F.3d at 576 n.7 (citing <i>Laxton</i>, 639 S.W.2d 431 and <i>Newsom</i>, 588 S.W.2d at 887). First, <i>Sutton</i> did not address <i>Potts</i>. See generally <i>Sutton</i>, 419 F.3d 568. Second, in <i>Newsom</i>, which involved a car accident in which the plaintiff was not only injured but “totally temporarily disabled at the time of the collision,” the court merely held that verdicts were not impermissibly inconsistent. <i>Newsom</i>, 588 S.W.2d at 884-88. Third, <i>Laxton</i> held that a plaintiff who ingests toxins may recover damages for the mental anguish between discovery of the ingestion and a negative diagnosis. 639 S.W.2d 433-34. Neither <i>Newsom</i> nor <i>Laxton</i> held that a plaintiff could recover the costs of a lifetime of future medical monitoring based solely on the risk of exposure to a possible carcinogen without any present injury. See <i>Jones</i>, 2000 WL 33727733, at *6 (analyzing <i>Laxton</i> and other Tennessee precedent and concluding they do not permit medical monitoring costs without present injury); see also <i>Camper v. Minor</i>, 915 S.W.2d 437, 445-46 (Tenn. 1996) (recognizing that <i>Laxton</i> questionably departed from the strict interpretation of the physical manifestation rule, which the court then abandoned as an element for the recovery of damages for severe mental anguish, but otherwise retained).</p> <p>Following <i>Sutton</i>, the Tennessee Supreme Court examined the requirements for recovering future medical expenses in <i>Rye v. Women’s Care Ctr. of Memphis, PLLC</i>, 477 S.W.3d 235, 266 (Tenn. 2015). There, the court reaffirmed the need to prove a physical injury to state a claim for future medical expenses. <i>Id.</i> (assuming, but not deciding, that RH-sensitization was a cognizable physical injury before concluding that <i>Rye</i> failed to prove a need for future medical care to reasonable medical certainty).</p> <p>Even if adopted, the <i>Restatement (Second) of Torts</i> § 7 provides no basis from which this Court could expand liability by predicting Tennessee would abandon the physical injury requirement. The purported need for medical monitoring based on a risk of harmful exposure and future disease, without present physical injury, is “not a legally protected interest” in Tennessee, and Plaintiffs identify no authority supporting the contrary conclusion.</p> <p>Further, Plaintiffs provide no basis from which to conclude conclusory assertions of subcellular or other physiological change constitute actionable harm under Tennessee law, particularly in light of <i>Potts</i>’s holding that exposure claims are not cognizable until the disease is diagnosable.</p>
Texas	<p>In the absence of Texas precedent on the need to plead and prove present physical injury for claims seeking to recover medical monitoring costs, the analysis properly focuses on precedent in related areas. <i>Travelers</i>, 594 F.3d at 244. And where precedent yields “two competing yet sensible interpretations of state law,” district courts are required to “opt for the interpretation that restricts liability, rather than expands it.” <i>A.I. Dupont Hosp. for Child.</i>, 393 F. App’x 884, 893 n.7. Applying this approach, <i>Norwood v. Raytheon Co.</i>, 414 F. Supp. 2d 659 (W.D. Tex. 2006) turned to analogous precedent: Texas’s requirement of a present physical injury in <i>Temple-Inland</i> to recover damages for mental anguish arising from the risk of future disease as a result of exposure. <i>Norwood</i> opted for the conservative prediction that Texas would also require present physical injury to sustain a claim for medical monitoring costs, particularly given that the claims are predicated on the risk of future disease from exposure and abandoning the physical injury requirement raises the same concerns regarding the validity of claims, unpredictable liability, and floods of trivial claims. 414 F. Supp. 2d at 662-68.</p> <p>Plaintiffs do not dispute <i>Norwood</i>’s analysis of Texas law on the application of the physical injury requirement to claims arising from an alleged increased risk of future disease. Rather, they</p>

REPLY CITATION TABLE A:**Respironics' Reply to Plaintiffs' Opposition Concerning Jurisdictions Requiring a Present Physical Injury for a Claim for Medical Monitoring**

States	Respironics' Reply
	<p>challenge <i>Norwood</i>'s reliance on <i>Temple-Inland</i> and rely instead on the belief that Texas would adopt <i>Restatement (Second) of Torts</i> § 7. Plaintiffs, however, provide no explanation for why reliance on <i>Temple-Inland</i> was erroneous, particularly given <i>Norwood</i>'s fulsome justification for doing so. Plaintiffs also identify no authority supporting their assertion that Texas would recognize the “economic loss” of future medical monitoring costs to be “a legally protected interest.” To the contrary, the <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1 recognizes there is no “duty to avoid the unintentional infliction of economic loss on another.”</p> <p>Plaintiffs also provide no basis from which to decide conclusory assertions of subcellular or other physiological change constitute actionable harm under Texas law.</p>
Virginia	<p>Despite Plaintiffs' misrepresentations to the contrary, both <i>Ball</i>, 958 F.2d 36, and <i>In re Chinese Drywall</i>, 2010 WL 7378659, addressed the question presented here: does Virginia permit claims seeking medical monitoring costs as a form of relief in the absence of present physical injury. <i>Ball</i> determined that Virginia law required present physical injury. 958 F.2d at 39. And <i>In re Chinese Drywall</i> reaffirmed this ten years later, holding “plaintiffs not presently claiming personal injuries” could not seek medical monitoring costs as damages because, while certain other states have permitted such a claim, Virginia had not, and adopting such a novel claim required the court to impermissibly depart from Virginia common law. 80 Va. Cir. 69, 2010 WL 7378659 at *9-10.</p> <p>Plaintiffs identify no authority to support their request to ignore this precedent and predict that Virginia would expand liability by abandoning the present physical injury requirement here. <i>Restatement (Second) of Torts</i> § 7, even if adopted by Virginia, merely defines “injury” as “the invasion of any legally protected interest of another,” and the alleged need for medical monitoring absent a physical injury is not a “legally protected interest” in Virginia. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p> <p>Likewise, Plaintiffs provide no basis from which to decide conclusory assertions of subcellular change constitute physical injury under Virginia law, particularly given the holding in <i>Lo v. Burke</i>, 455 S.E.2d 9 (Va. 1995) that the cellular growth of a cyst is not an actionable injury until it turns malignant. <i>Id.</i> at 13.</p>
Washington	<p>Washington tort law requires “a present, existing injury” to establish liability. <i>Duncan</i>, 203 F.R.D. 601, 606 (citing <i>Koker v. Armstrong Cork, Inc.</i>, 804 P.2d 659, 668-69 (Wash. Ct. App. 1991); <i>Sorenson v. Raymark Indus., Inc.</i>, 756 P.2d 740, 741-42 (Wash. Ct. App. 1988)). “An enhanced risk of disease is not enough.” <i>Duncan</i>, 203 F.R.D. at 606 (citing <i>Koker</i>, 804 P.2d at 669). From this, <i>Duncan</i> held that the “elements of negligence are clear in Washington,” apply to claims seeking medical monitoring costs as a form of damages, and require existing injury. <i>Id.</i> at 609. Plaintiffs' assertion that <i>Duncan</i>'s analysis has no bearing on whether Washington requires physical injury, ignores the decision's detailed holding.</p> <p>Plaintiffs identify no authority to support their request to ignore <i>Duncan</i> and Washington precedent to predict that Washington would expand liability by abandoning the present physical injury requirement here. <i>Restatement (Second) of Torts</i> § 7, even if adopted by Washington, merely defines “injury” as “the invasion of any legally protected interest of another.” Freedom from “economic loss”—here, the potential future incurrence of medical monitoring costs—allegedly caused by unintentional conduct is not a “legally protected interest” in Washington. Indeed, permitting the recovery of “economic loss” here, as Plaintiffs suggest, would be contrary to <i>Restatement (Third) of Torts: Liab. for Econ. Harm</i> § 1.</p>

CERTIFICATE OF SERVICE

I hereby certify that on April 21, 2023, the foregoing document was electronically filed with the Clerk of the Court and served upon counsel of record through the Court's ECF system.

/s/ John P. Lavelle, Jr.
John P. Lavelle, Jr.